

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

4 - - -

5
6 IN RE: NATIONAL : HON. DAN A.
7 PRESCRIPTION OPIATE : POLSTER
8 LITIGATION :
9 :
10 APPLIES TO ALL CASES : NO.
11 : 1:17-MD-2804
12 :

13 - HIGHLY CONFIDENTIAL -

14 SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

15 VOLUME I

16 - - -

17 April 17, 2019

18 - - -

19 Videotaped deposition of
20 THOMAS PREVOZNIK, taken pursuant to
21 notice, was held at the law offices of
22 Williams & Connolly, 725 12th Street,
23 Washington, D.C., beginning at 9:11 a.m.,
24 on the above date, before Michelle L.
25 Gray, a Registered Professional Reporter,
26 Certified Shorthand Reporter, Certified
27 Realtime Reporter, and Notary Public.

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16 (Via telephone)
(Motley Rice)

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18 VIDEOTAPE TECHNICIAN:
Chris Ritona

19

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1 - - -
 2 I N D E X
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6 PAGE LINE

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THE VIDEOGRAPHER: We are

3

now on the record. My name is

4

Chris Ritona. I am the

5

videographer with Golkow

6

Litigation Services.

7

Today's date is April 17,

8

2019, and the time is

9

approximately 9:11 a.m.

10

This video deposition is

11

being held at Williams & Connolly,

12

LLP, 725 12th Street Northwest,

13

Washington, DC, in the matter of

14

National Prescription Opiate

15

Litigation, MDL No. 2804, case

16

Number 17-MD-2804, for the United

17

States District Court, Northern

18

District of Ohio, Eastern

19

Division.

20

The deponent today is Thomas

21

Prevoznik. And all counsel will

22

be noted upon the stenographic

23

record.

24

The court reporter today is

1 Michelle Gray, and she will now
2 please swear in the witness.

3 - - -

4 ... THOMAS PREVOZNIK, having
5 been first duly sworn, was
6 examined and testified as follows:

7 - - -

8 EXAMINATION

9 - - -

10 BY MS. MAINIGI:

11 Q. Good morning, Mr. Prevoznik.

12 A. Good morning.

13 Q. I will begin the
14 questioning. My name is Enu Mainigi, and
15 I'm going to begin the questioning on
16 behalf of the defendants, and then there
17 are other defendants that may question
18 you after I'm done, and then the
19 plaintiffs will question you thereafter.

20 Mr. Prevoznik, I have put in
21 front of you Exhibit 1. And Exhibit 1 is
22 the notice of deposition.

23 (Document marked for
24 identification as Exhibit

1 DEA-Prevoznik-1.)

2 (Document marked for
3 identification as Exhibit
4 DEA-Prevoznik-2.)

5 BY MS. MAINIGI:

6 Q. The notice of videotaped
7 30(b)(6) deposition for your testimony
8 today.

9 Do you see that?

10 A. Yes, I do.

11 Q. And do you see that attached
12 to the notice is a letter dated March 22,
13 2019, from the Department of Justice
14 addressed to myself, and Ms. Singer of
15 Motley Rice?

16 A. Yes.

17 Q. Have you had a chance to
18 review, either alone or with your
19 counsel, the substance of this March 22nd
20 letter as well as the notice of
21 deposition?

22 A. Yes, I have.

23 Q. And do you understand that
24 you are here today testifying in a

1 30(b)(6) capacity on behalf of the Drug
2 Enforcement Administration?

3 A. Yes, I do.

4 Q. And as I understand it, you
5 will be testifying as to certain topics
6 designated consistent with the letter
7 dated March 22, 2019, correct?

8 A. Correct.

9 Q. Okay. Now, if you could
10 turn to the letter itself, Mr. Prevoznik.
11 And I'm looking specifically at Page 2 of
12 the letter.

13 A. Okay.

14 Q. You have been designated to
15 provide testimony on Topic 2, DEA's
16 interpretation and enforcement of and
17 practices related to 21 U.S.C. Section
18 823 and 21 C.F.R. Section 1301.74,
19 subject to the limitations set forth by
20 DOJ in this letter, correct?

21 A. Correct.

22 Q. How -- I notice,
23 Mr. Prevoznik, that Exhibit 3 that is in
24 front of you, is a deposition prep chart,

1 correct?

2 A. Correct.

3 (Document marked for
4 identification as Exhibit
5 DEA-Prevoznik-3.)

6 BY MS. MAINIGI:

7 Q. Could you -- and feel free
8 to refer to that. Could you at a high
9 level explain to me how you set about
10 preparing for Topic 2?

11 A. I reviewed some of the
12 letters, the guidance that was sent out
13 to the registrant community.

14 I reviewed some of the
15 conference materials that were given at
16 registrant conferences that we've held.

17 I've also reviewed some of
18 the MOAs that were agreed upon and
19 settled with some of the registrants.

20 I met with -- I met with and
21 I discussed with fellow DEA colleagues
22 about -- whether it was cases that they
23 had against the defendants or that they
24 had knowledge of some of the policies and

1 practices that DEA has had regarding the
2 suspicious orders.

3 Q. Do you recall, and I realize
4 this is somewhat difficult to segregate
5 out in your mind. But looking at
6 Exhibit 3, are you able to identify for
7 me the particular individuals you spoke
8 to in relation to Topic 2?

9 A. Well, definitely Nancy
10 Jackson and Mark Armstrong. Nancy Kent,
11 Lenny Levin, Lisa Sullivan, Dave White,
12 Donna Richards, as well as Scott Collier,
13 Ruth Carter, Susan Langston, Loren
14 Miller, and -- oh, Chris Grush and Scott
15 Brinks, Scott Garriott, Lynette Wingert,
16 June Howard, Matt Strait, Kerry Hamilton,
17 Justin Wood.

18 That's probably the best of
19 my recollection at this point.

20 Q. Thank you, Mr. Prevoznik.

21 Just taking a look at
22 Exhibit 3, entitled "Prevoznik Deposition
23 Prep," is it fair to say that essentially
24 with respect to Topic 2, you spoke to

1 essentially everybody that's on this list
2 except for the attorneys that are
3 representing you from DOJ and DEA?

4 A. Oh, I'm sorry. No, I talked
5 to them as well.

6 Q. Okay.

7 A. I apologize for that.

8 Q. No, no, no. And let me be
9 clear. Is there anyone that works at DEA
10 that you didn't speak to with respect to
11 Topic 2 that's listed here on Exhibit 3?

12 A. I think I was pretty
13 thorough on listing everybody. I
14 apologize if I did not get everybody, but
15 I think I got everybody.

16 Q. That's completely fine.
17 Did you speak to Joe
18 Rannazzisi in preparation for today's
19 deposition?

20 A. No, I have not.

21 Q. Did you speak to Kyle Wright
22 in preparation for today's deposition?

23 A. No, I have not.

24 Q. Are you aware that

1 Mr. Wright was deposed in this matter
2 recently?

3 A. Yes.

4 Q. Did you have occasion to
5 review his deposition transcript?

6 A. I reviewed his questions.

7 Q. You reviewed only the
8 questions that were asked of him at his
9 deposition?

10 A. Correct.

11 Q. You were not provided the
12 opportunity to review the answers?

13 A. I was given the questions.
14 That's what I reviewed.

15 Q. Did you speak to Demetra
16 Ashley in preparation for today's
17 deposition?

18 A. No, I did not.

19 Q. Did you review -- were you
20 aware that Ms. Ashley was deposed in this
21 matter recently?

22 A. Yes.

23 Q. Did you review Ms. Ashley's
24 deposition transcript in preparation for

1 today's deposition?

2 A. Yes, I did.

3 Q. Did you review the entirety
4 of the deposition transcript?

5 A. Yes, I did.

6 Q. Can you explain to me your
7 understanding as to why you only reviewed
8 the questions and not answers for
9 Mr. Wright's deposition transcript?

10 MR. FINKELSTEIN: I'm going
11 to object and instruct you not to
12 answer to the extent that your
13 answer would call for
14 communications with either DOJ or
15 DEA attorneys.

16 THE WITNESS: Based on the
17 advice of my attorney.

18 BY MS. MAINIGI:

19 Q. Did you speak with Mr. Mapes
20 in preparation for today's deposition?

21 A. No, I did not.

22 Q. Did you familiar with
23 Mr. Michael Mapes?

24 A. I know who he is, yes.

1 Q. And are you aware that
2 Mr. Mapes was involved with
3 communications to distributors in various
4 time periods while he was at DEA?

5 A. Yes.

6 Q. Who made the decision as to
7 the individuals that you would speak to
8 in preparation for today's deposition?

9 A. I did.

10 Q. And how did you go about
11 making the determination as to which
12 individuals to speak with versus not?

13 A. I mean, I've been on the job
14 28 years. So I know quite a few people.
15 I reached out to the main people that I
16 knew would have information, and based on
17 discussing with them, there were
18 suggestions made to reach out to other
19 people. Some of the people I worked with
20 in headquarters and I worked closely with
21 them, so I -- I knew they knew
22 information that could help me prepare.
23 So that -- that's how I figured out who I
24 should be talking to.

1 But I did consult with DEA
2 and DOJ attorneys on who I was going to
3 talk to.

4 Q. Did you reach out to any
5 former employees of DEA as part of your
6 preparation?

7 A. No.

8 Q. Taking a look at -- and --
9 and I'll come back to the list of
10 individuals that you -- you gave me,
11 Mr. Prevoznik, and -- and perhaps inquire
12 some further about those particular
13 conversations in a few minutes.

14 Did you keep notes of those
15 conversations by any chance?

16 A. No, not really.

17 Q. Have you --

18 A. I mean I had some -- some
19 e-mails from them with like, case
20 investigations. I asked them to
21 summarize them, the cases, so I -- I do
22 have those. Mostly it was just oral
23 communication.

24 Q. How did you -- now you --

1 you met with these individuals over a
2 pretty wide span of time, beginning it
3 looks like all the way back to perhaps
4 late January, early February, correct?

5 A. Correct.

6 Q. And now we are in mid April.
7 How did you keep track of all of the
8 information that you learned from these
9 individuals if you didn't take notes of
10 those conversations?

11 A. Well, like I said, I did
12 have some e-mails with them, but in
13 essence, I pretty much -- we would go
14 over certain topics. We would listen.
15 And then with DOJ attorneys and DEA
16 attorneys, we would discuss that. So
17 each time we met, we met on a weekly
18 basis, we would go over the same -- same
19 topics, so that it was -- we started to
20 come together on what are -- what are the
21 policies and procedures that DEA has
22 articulated to the registrants.

23 So it was just a natural
24 progression of constantly going over the

1 material with them.

2 Q. And do you have, for each
3 one of the topics, certain talking points
4 that you have or certain Q&A that you
5 have prepared to utilize today?

6 MR. FINKELSTEIN: Object to
7 the form.

8 THE WITNESS: Well, I mean I
9 put together the binder to help
10 guide me, so a lot of the
11 documents are -- come from those
12 conversations of -- throughout the
13 years of what we've done, so
14 that's kind of what the binder is,
15 a guide of that.

16 MS. MAINIGI:
17 Mr. Finkelstein, could we get a
18 copy of -- oh, thank you. We've
19 got a copy of the binder.

20 BY MS. MAINIGI:

21 Q. With respect to the e-mail
22 exchanges that you had with some certain
23 of these witnesses, were those e-mails
24 where they were forwarding you prior

1 contemporary -- prior e-mails from other
2 time periods, or were those e-mails where
3 they were answering questions that you
4 had?

5 A. Answering questions that I
6 had.

7 Q. So for example, you may have
8 asked a witness to answer a particular
9 question or refresh you as to a
10 particular settlement with a defendant.
11 And that individual provided an answer to
12 you via e-mail?

13 A. Correct.

14 Q. And are those e-mails
15 included in the binder?

16 A. No, they are not.

17 Q. Okay.

18 MS. MAINIGI: Counsel, we
19 don't have to delay on this right
20 now, but we'd like to make a
21 request to get those e-mails
22 please.

23 MR. FINKELSTEIN: We'll take
24 it under advisement.

1 BY MS. MAINIGI:

2 Q. Mr. Prevoznik, taking a look
3 at Topic 3, which is on Page 3 of the
4 March 22nd letter.

5 Is it fair to say that you
6 have also been designated to provide
7 testimony on Topic 3, which is DEA's
8 guidance and communications regarding the
9 criteria for what makes a controlled
10 substances order suspicious, subject
11 again to the limitations set forth by DOJ
12 in this letter?

13 A. Correct.

14 Q. Would it be fair to say that
15 your preparation for Topic 3 is
16 consistent and essentially overlaps with
17 your preparation for Topic 2?

18 A. Yes.

19 Q. In terms of the time period
20 that you prepared for, Mr. Prevoznik, is
21 it fair to say that you prepared back to
22 the 1996 time period?

23 A. Yes.

24 Q. Could you name for me, from

1 your --

2 A. Actually, if I could --

3 Q. Please.

4 A. I did -- I did review some
5 other stuff prior to 1996 as well.

6 Q. Okay. And that would be
7 documents prior to 1996?

8 A. Yes.

9 Q. Okay. What documents that
10 you recall did you review prior to 1996?

11 A. It was the press release
12 from a 1984 Burroughs Wellcome civil
13 settlement. It was also some
14 correspondence between registrants and
15 DEA headquarters regarding suspicious
16 orders.

17 Q. Anything else that you
18 remember from the pre-'96 time period?

19 A. Not off the top of my head.

20 MS. MAINIGI: Counsel, I
21 will ask you one question. All
22 the documents that Mr. Prevoznik
23 reviewed, for the purpose of his
24 preparation here today, perhaps

1 with the exception of those
2 e-mails that we referenced, have
3 all those documents been produced?

4 MR. FINKELSTEIN: I can look
5 into it.

6 MS. MAINIGI: If you could
7 let us know sometime this morning,
8 that would be helpful.

9 MR. FINKELSTEIN: I'll say
10 that we've produced everything
11 that we've agreed to produce
12 pursuant to the agreed-upon
13 protocol.

14 MS. MAINIGI: Okay. We can
15 pick that up during a break.

16 BY MS. MAINIGI:

17 Q. Mr. Prevoznik, with respect
18 to, let's say, the earlier time period
19 for which you prepared, approximately
20 1996 to, let's call it 2003-2004, can you
21 highlight for me the specific individuals
22 that you named before, who you spoke to
23 that were there during that time period,
24 and you may have gotten information from

1 them about that time period?

2 A. Can I ask for a
3 clarification on what do you mean by,
4 that were -- where?

5 Q. I apologize, at the DEA. So
6 let me -- let me -- let me divide that up
7 into -- into smaller pieces.

8 You prepared back to 1996
9 and in some cases earlier, correct?

10 A. Correct.

11 Q. Who were the individuals
12 that you spoke to, to prepare yourself to
13 cover questions regarding the time period
14 of 1996 to 2003?

15 A. Loren Miller. Jim Arnold.

16 Q. Could you speak up?

17 A. Jim Arnold. Lauren Miller.
18 Ruth Carter. Susan Langston. Scott
19 Collier. Lanette Wingert. Scott
20 Garriott I think that's -- those are the
21 DEA folks.

22 Q. Thank you, Mr. Prevoznik.
23 If anybody else comes to mind, just
24 please let me know.

1 A. Sure.

2 Q. If they do.

3 Now continuing on just in
4 terms of identifying the topics. You
5 have also been designated to provide
6 testimony on Topic 9 subject to the
7 limitations set forth by DOJ, correct?

8 A. Is that Page 5?

9 Q. It is Page 5, yes.

10 A. Correct.

11 Q. And that topic, again
12 subject to the limitations laid out in
13 the letter, is your procedures and
14 practices relating to obtaining,
15 processing, analyzing and taking formal
16 or informal actions based upon ARCOS
17 data, suspicious order reports or other
18 communications from DEA registrants to
19 identify and stop sources of diversion.

20 Is that correct?

21 A. Correct.

22 Q. How did you prepare to
23 testify on this particular topic,
24 Mr. Prevoznik?

1 A. Similar fashion to how I did
2 it with the SORs. I also did it with
3 ARCOS. Primarily I talked to June
4 Howard, Hope Thomas, and Nancy Kent.

5 Q. What was the first name?
6 I'm sorry. I missed it.

7 A. Hope Thomas? Hope.

8 Q. Prior to Hope Thomas?

9 A. Nancy Kent or --

10 Q. Was it June?

11 A. June Howard.

12 Q. June Howard. Thank you.

13 A. And Nancy Jackson.

14 MR. FINKELSTEIN: Can I just
15 interject. Hopefully this will
16 make the transcript clearer. The
17 witness said SORs, S-O-R-S, not
18 source.

19 BY MS. MAINIGI:

20 Q. And, Mr. Prevoznik, you have
21 also been designated to testify -- excuse
22 me, provide testimony on Topic 12, again,
23 subject to the limitations set forth by
24 DOJ, correct?

1 A. Correct.

2 Q. And Topic 12 is your
3 decision not to allow DEA-registered
4 distributors access to deidentified ARCOS
5 data prior to February 2018, and your
6 decisions to provide DEA-registered
7 distributors with limited access to
8 certain ARCOS data in February, correct?

9 A. Correct.

10 Q. Is there anyone else you
11 spoke with in preparation for your
12 deposition Mr. Prevoznik, that you have
13 not identified thus far?

14 A. I don't think I've orally
15 identified the DEA and DOJ attorneys. If
16 you want me to.

17 Q. Setting aside the DOJ/DEA
18 attorneys, are there any other
19 individuals with whom you spoke in
20 preparation for your deposition that you
21 have not identified so far?

22 A. Not that I can recall.

23 Q. Okay. Are there any
24 deposition transcripts other than

1 Mr. Wright's partial transcript and
2 Ms. Ashley's full transcript that you
3 reviewed in preparation for today's
4 deposition?

5 A. Deposition testimonies?

6 Q. Yes.

7 A. No. I -- no.

8 Q. With respect to documents,
9 Mr. Prevoznik, obviously I appreciate you
10 bringing along today a binder of
11 materials that you've reviewed. I'm
12 assuming that's probably only a partial
13 set of the documents you reviewed in
14 preparation for today; is that correct?

15 A. Correct.

16 Q. Can you describe for me what
17 other documents or types of documents you
18 recall reviewing in preparation for your
19 deposition today?

20 A. Sure. I reviewed the energy
21 and commerce report. I reviewed the GAO
22 reports. I don't have the specific dates
23 off the top of my head. But I reviewed
24 those.

1 I've reviewed federal
2 register notices. I reviewed memorandums
3 of agree -- of agreement.

4 I reviewed settlements. I
5 reviewed policy letters, as I had already
6 previously stated. I reviewed, again,
7 presentations, whether it was
8 presentations to conferences or whether
9 it was presentations from, like, ARCOS,
10 we give a presentation, I reviewed those
11 presentations. I think that pretty much
12 covers it.

13 Q. How did you determine which
14 documents to review in preparation for
15 your deposition?

16 A. Well, as you'll note on my
17 prep sheet, we met on a weekly basis, so
18 we had constant conversation -- constant
19 conversations about, you know, this
20 topic. We need to cover this topic, so
21 here is some suggestions. Or I would
22 say, is this something to review. And
23 that's kind of how we formulated the game
24 plan of which documents to review.

1 Q. So fair to say the witnesses
2 or the individuals with whom you spoke or
3 who you interviewed for -- to prepare
4 today, might have brought certain
5 documents to your attention as part of
6 that process?

7 A. Well, I mean, I'm familiar
8 with the big national cases, so I know --
9 I knew where those documents were. So
10 they didn't have to provide them. I knew
11 where they were, so...

12 Q. In terms of policy
13 documents, for example, where did you get
14 those?

15 A. From our policy unit. That
16 would be Jim Arnold and Loren Miller.

17 Q. And with respect to, for
18 example, communications with distributors
19 or other registrants that took place over
20 the years, where did you go to get those?

21 A. So those were in our
22 regulatory section. And they provided
23 those.

24 Q. And remind me,

1 Mr. Prevoznik, who are the individuals
2 from the regulatory section that you
3 spoke with?

4 A. Well, these are all the
5 people that were there for that time
6 period, so it was Lenny Levin, Lisa
7 Sullivan, Donna Richards, Dave White. I
8 mean, I've been in headquarters since
9 April 2012. So I kind of know where --
10 who has the documents. It's not hard for
11 me to go ask somebody to go pull it.

12 I believe this was all part
13 of the documents for this litigation
14 anyway that were being pulled, so...

15 Q. I'm going to come back,
16 Mr. Prevoznik, on some of those
17 conversations you had. And I'm going to
18 spend a little bit of time with you now
19 on your background.

20 A. Sure.

21 Q. As I understand it, you
22 currently work for DEA; is that correct?

23 A. Yes.

24 Q. And what is your position?

1 A. I am currently the acting
2 section chief of the pharmaceutical
3 investigations in the diversion control
4 division.

5 Q. And Mr. Prevoznik, you are
6 somewhat soft-spoken. If you could keep
7 your voice up.

8 A. I apologize. I could be
9 loud. I just --

10 Q. I completely understand.
11 And in -- how long have you
12 had that position?

13 A. I've been acting since
14 mid-January of this year.

15 Q. How long have you been at
16 DEA overall?

17 A. Over 28 years.

18 Q. And is it fair to say that
19 part of the time that you were at DEA,
20 you were in the field, one of the field
21 offices, or several field offices, and
22 part of the time you've been at DEA
23 you've been at corporate headquarters?

24 A. I've been in the field.

1 I've been in our training academy as an
2 instructor, and I've also went back to
3 the field, and then to headquarters.

4 Q. Your current position is at
5 headquarters, correct?

6 A. Correct.

7 Q. And what -- in that
8 position, do you have any oversight or
9 responsibility related to suspicious
10 order monitoring or reporting?

11 A. Yes. My -- well, they just
12 split our unit, our section to a -- so
13 that analytics side, which was ARCOS,
14 which includes drug theft loss, and SORs
15 data, the output side. They've been
16 moved to another section. That was like
17 two weeks ago. But prior to that it'd
18 been under -- under me.

19 Q. So it was primarily the
20 analytics unit in your current role that
21 had some degree of interaction with
22 suspicious order monitoring or reporting?

23 A. Well, I'd like to clarify.
24 Because headquarters, we're only --

1 currently we're only receiving those
2 suspicious orders that come to us via an
3 MOA that has been entered with the
4 registrants that have gotten in trouble
5 with us or have -- have had an action
6 taken against them by us. So that those
7 that have been required to report, those
8 who report centrally electronically to us
9 at headquarters, we had those.

10 But regulation requires that
11 actually -- the suspicious orders go to
12 the field, the local field office. So
13 you have two different pots of suspicious
14 orders. So we don't see what the field
15 gets.

16 Q. So by regulation, suspicious
17 order reporting from distributors or
18 other registrants goes to the DEA field
19 offices, correct?

20 A. Correct.

21 Q. And the DEA field offices
22 make a determination as to whether any of
23 those suspicious order reports get
24 forwarded on to headquarters, is that

1 right?

2 A. No. That's not correct.

3 The field --

4 Q. Who makes that decision?

5 A. Well, no, the -- I'm sorry,
6 if I didn't explain to you correctly.

7 But those that have had some sort of
8 administrative action taken against them,
9 in particular regarding suspicious
10 orders, if they've had an action taken in
11 the past -- it started in 2008 where we
12 required them to report electronically
13 and centrally to headquarters, so that
14 those suspicious orders come to
15 headquarters.

16 But if they haven't had an
17 administrative action and haven't been
18 directed to send it to headquarters, the
19 regulation requires that they submit them
20 to the field office. The field office
21 will make the determination of what
22 action they're going to take. So we
23 don't get -- headquarters does not get
24 involved in those actions of determining

1 what to do. Those are field decisions.

2 Q. So since 2008, suspicious
3 orders from any registrant who has had an
4 administrative action taken, sends their
5 suspicious orders to headquarters?

6 A. Well, I want to be careful
7 of the -- the way that you're phrasing
8 "any administrative action." These
9 are -- these are settlement agreements
10 between us and the registrant,
11 typically -- or they have been because
12 they've had difficulty reporting
13 suspicious orders. So we've had civil
14 settlements, part of the settlement
15 agreements were they will report to
16 headquarters. Those are the ones that
17 have that.

18 We have taken other
19 administrative actions against other
20 registrants. It may not be -- if it has
21 nothing to do with suspicious orders,
22 then that would not be part of the
23 settlement or the agreement. So...

24 Q. The suspicious orders that

1 are being sent to headquarters per the
2 direction of the DEA for those
3 registrants who may have entered into
4 settlements and the like after 2008, are
5 they also being sent to the field
6 offices?

7 A. So the field actually has
8 access to them. So they can go in and
9 see them. So there's actually -- within
10 our system there's actually two sets of
11 SORs. One is what we call Legacy, that's
12 the older system. So that's the ones
13 that the MOAs have -- they are the older
14 MOAs.

15 Whereas the vetted side is
16 the newer side. And what we've done,
17 we've -- we've actually changed it. So
18 that it still goes -- the SORs system
19 through the vetted side is like -- is on
20 the ARCOS platform. So that the -- the
21 distributors or the manufacturers are
22 familiar with what the ARCOS platform is,
23 so that when it comes in, it gets vetted,
24 so it get -- gets a QA, quality assurance

1 check. So that if there are issues with
2 what they are reporting, they have to fix
3 it before we will accept it. So that's
4 the -- that's the newer system.

5 Q. So just for clarification of
6 the record, Mr. Prevoznik. Can you give
7 us just a high level definition or
8 explanation of the SORs system, what that
9 is?

10 A. Well, which one? The one
11 that goes to the field, the one that's
12 Legacy? Because we still have
13 registrants that are still submitting via
14 the Legacy system. And we have a
15 registrant now that is under a current
16 MOA that is filing it in the vetted
17 system.

18 Q. The Legacy system is
19 referred to as what?

20 A. We just call it -- they are
21 both SORs, but we call it Legacy.

22 Q. Okay. So let's start with
23 the Legacy SORs system. Can you describe
24 what that is?

1 A. So it's a system, electronic
2 system in which the registrants that are
3 continuing to report their suspicious
4 orders electronically from their past
5 MOAs, they can upload their information
6 into that system. We don't force vet it,
7 because that was not what we did in the
8 past. So that, that was the change to
9 force vet it. So the newer system has
10 the force vetting. That's really the
11 only difference between it.

12 Q. What is that term you used,
13 "force vetting"? What does that mean?

14 A. So if -- if the -- if say an
15 NDC number is wrong or a DEA registration
16 number is wrong, it's going to -- it's
17 going to say to the registrant that's
18 trying to upload it, we need to correct
19 this. So it's correcting -- it's -- it's
20 force correcting the information so that
21 when it comes in it's clean and accurate.

22 Q. And the Legacy system, the
23 field office -- the field offices have
24 access to the Legacy system?

1 A. They have access to both.

2 Q. And does headquarters have
3 access to the Legacy system?

4 A. We have access to both.

5 Q. And then what is your
6 terminology or how do you refer to the
7 non-Legacy system?

8 A. The which one?

9 Q. The non-Legacy system, the
10 more updated system--

11 A. Right now we just -- it's --
12 we both refer to it as SORs. But when
13 you go in, the vetted one is the one that
14 you see first. But you can -- there's a
15 link to go to Legacy. So you can toggle
16 between the two.

17 Q. So just two different
18 databases essentially that exist?

19 A. Essentially.

20 Q. Okay. Both containing
21 suspicious order reporting from
22 registrants?

23 A. Those that had -- through
24 the settlements had -- were required

1 to -- to send it in.

2 Q. And --

3 A. Because you have the -- you
4 still had the field ones as well.

5 Q. I was just going to get to
6 that next. So those that have not been
7 required to send in their suspicious
8 order reporting to the SORs system, where
9 are those suspicious orders stored?

10 A. Well, those go to -- those
11 go to the field. So the field takes
12 them, reviews them, makes the
13 determination of what action they deem
14 necessary at that point.

15 Q. And those suspicious orders
16 are reported to the field, as a general
17 matter, electronically; is that right?

18 A. No. I mean they could come
19 in e-mail, it could be attached to an
20 e-mail, like a spreadsheet. They come in
21 as -- I know it's hard to believe, but
22 people still fax. It comes in snail
23 mail, various different forms.

24 Q. And ultimately the field

1 offices make a determination as to what
2 to do with any of the suspicious order
3 reports that come into the field offices?

4 A. Yes. Because one thing
5 that -- that we do is if a registrant
6 sends in a suspicious order and it's not
7 in our area of responsibility, we would
8 then forward it to that office that that
9 falls under, because we wouldn't know
10 that registrant. So we'd send it -- so
11 if it's not in our AOR, area of
12 responsibility, we would then send it to
13 that office for them to review.

14 Q. Is -- is there some way for
15 corporate to regularly be apprised of
16 what the field offices are doing with the
17 suspicious order reports that come into
18 them?

19 A. Apprised in what way?

20 Q. How -- does corporate know,
21 as a general matter, what happens with a
22 suspicious order reporting that goes just
23 to the field offices?

24 A. I don't know. I don't know

1 if they -- I mean, we use them for a
2 variety of different reasons. Some --
3 sometimes it's to corroborate
4 investigations. Sometimes it starts an
5 investigation. So if we're in the middle
6 of an investigation, we're not going
7 to -- we're not going to show our hand
8 whether we're doing something with it or
9 not. We're going to investigate. Which
10 is what we do.

11 Q. So some of the suspicious
12 order reporting that comes in, whether
13 through the field office or to
14 headquarters, may be utilized to start an
15 investigation, true?

16 A. True.

17 Q. Or it may be used to
18 corroborate perhaps an ongoing
19 investigation, true?

20 A. True.

21 Q. Any other uses of the
22 suspicious order reporting that may come
23 to the field offices or to headquarters?

24 A. It would also be used in our

1 scheduled investigations. That's when
2 we're out at the registrants and we use
3 it to review the suspicious ordering
4 monitoring system that they have in place
5 to ensure that they are actually doing
6 what they say they are going to do.

7 Q. Any other uses?

8 A. I mean they are used for
9 administrative actions. They are used
10 for civil, criminal, federal, state
11 cases.

12 Q. Can you define for us what
13 ARCOS data is?

14 A. Sure. ARCOS data is
15 required reporting by manufacturers and
16 distributors of all Schedule I and II,
17 III narcotics, and GHB, gamma hydroxide
18 butyric I believe. I hope I didn't
19 butcher that one, but GHB.

20 So that's what's required to
21 be reported through ARCOS.

22 Q. And how often is it required
23 to be reported?

24 A. Monthly or quarterly.

1 Q. And do you know
2 approximately for how long ARCOS data has
3 been required to be reported monthly or
4 quarterly?

5 A. I think -- I mean, it's been
6 part of the statute since the beginning,
7 so...

8 Q. So at least since 1996?

9 A. Oh before that, yeah.

10 Q. And does the ARCOS data
11 reporting go to headquarters or the field
12 offices?

13 A. Headquarters.

14 Q. Not to the field offices?

15 A. Field offices now have
16 access to it, yeah. I mean.

17 Q. And how long has that been
18 the case?

19 A. They've had -- we've had
20 access for a while. But it's -- it's
21 changed over the years.

22 Up until the fall of 2009 it
23 was on the mainframe. So the
24 capabilities were more -- we have

1 programmers that provided the details of
2 like what we could look at, whereas once
3 it went off the mainframe, then it become
4 more client service, so that the field
5 could actually do more things with it.
6 So that was roughly the fall -- fall of
7 2009 when it went off the mainframe.

8 Q. To your understanding, what
9 are the uses of the ARCOS data?

10 A. Well, it was originally for
11 UN reporting, so it was -- it's used for
12 UN reporting. It's used for quotas.
13 It's used to show trends. It's used in
14 our investigations, you know,
15 administrative, civil, criminal. It
16 supports investigations. We share it
17 with other federal agencies or state
18 agency, law enforcement, regulatory
19 agencies as well that are all, you know,
20 working to combat the diversion of
21 controlled substances. So it's working
22 with them in corroboration on
23 investigations. So it's used in various
24 means.

1 Q. Thank you. We'll come back
2 to ARCOS data in a little bit. Let me
3 take you back -- we took a bit of a
4 tangent on the data, but that was very
5 helpful. Thank you.

6 Let me bring you back to
7 your job responsibilities currently. And
8 analytics, which is where SORs and ARCOS
9 is, used to be underneath you, but has
10 moved in the last couple of weeks, true?

11 A. True.

12 Q. And I apologize. You
13 probably told me. But what department
14 did it move over to?

15 A. It's actually a new section.

16 Q. So it's now --

17 A. It's still in diversion
18 control division. It's -- but we just
19 put a new section up.

20 Q. And what was the reason to
21 create a separate section within
22 diversion control for the analytics unit?

23 A. Well, my section, is the
24 biggest -- was the biggest section within

1 the diversion control division.

2 We have, under my section,
3 we have mobile -- two mobile diversion
4 tactical squads. We have the case
5 coordination unit. Then we had the ARCOS
6 unit. So I just had a lot of people
7 under me.

8 We -- in the pharmaceutical
9 investigations section, we provide a lot
10 of guidance and assistance to the field,
11 you know, financial, equipment, that kind
12 of thing. So we also have various other
13 units that help support the field that's
14 out in the field, to help support.

15 Q. So is it fair to say that
16 the primary purpose then of your current
17 unit, the pharmaceutical investigations
18 section, is to provide support to the
19 field and their various investigations?

20 A. Correct.

21 Q. And those are investigations
22 that they may conduct of registrants,
23 individuals, doctors, and the like?

24 A. Correct.

1 Q. And they --

2 A. And if I may, we also work
3 very closely with our chief counsel on
4 orders to show cause and any
5 administrative actions that were -- that
6 were being looked at.

7 Q. Now, prior to your current
8 title, which is section chief of
9 pharmaceutical investigations, you were
10 the unit chief in the same section; is
11 that right?

12 A. No. So in January 2017, I
13 got promoted to the associate section
14 chief up in pharmaceutical
15 investigations.

16 Prior to that I was the unit
17 chief down in our policy and liaison
18 section. But I was the unit chief over
19 liaison.

20 Q. And give me a high level
21 description of what your role was there.
22 Or let's start with this. So that may be
23 a little too much to bite off.

24 Can you just again describe

1 for me at a high level what the purpose
2 of the unit is or the primary goals of
3 the unit?

4 A. Well, I mean, what I did was
5 I coordinated conferences, whether it was
6 the pharmacy diversion awareness
7 conferences. I gave a lot of
8 presentations. We would have to -- we
9 would coordinate with various entities to
10 try to get continuing education credits
11 for the pharmacists, and the techs. We
12 would do the DEA general conference --
13 conferences. You know, the distributor
14 conference. We would help our quota unit
15 with setting up the manufacturing
16 training that they would do.

17 I mean, we were like the
18 spokespeople, as well as coordinating the
19 events themselves.

20 Q. In the liaison unit, were
21 you speaking primarily with particular
22 groups as a whole, or did you have
23 one-off conversations with particular
24 registrants?

1 A. I'm not sure what you mean.

2 Q. Well, for example, could a
3 registrant call the liaison unit to ask
4 questions?

5 A. If they called us, it was
6 typically to set up a meeting.

7 If it was more specific
8 questions regarding issues or something,
9 that would be our policy section.

10 Q. And if a registrant was
11 calling the liaison unit to set up a
12 meeting, what type of meeting would that
13 be?

14 A. It could be the company
15 wants to present new products they have
16 down the line. It could be -- I'm trying
17 to think.

18 Some of it had to do with
19 treat -- they -- some type of, you know,
20 addiction treatment, that kind of thing,
21 where they wanted to talk about, you
22 know, could they get waivers on how
23 many -- you know, were they really -- you
24 know, was -- their product was so

1 different, could they, you know, not
2 have -- be limited to 100 data waive.
3 That kind of question.

4 It could be -- it runs the
5 gamut where -- a question the registrant
6 may have, so...

7 Q. Let me ask it this way.

8 The liaison unit, what
9 interaction did the liaison unit have
10 with suspicious order monitoring or
11 reporting?

12 A. I mean, at the conferences,
13 I mean, I gave presentations in 2013 and
14 '15 to the distributor -- at the
15 distributor conferences. So, I mean, I
16 know I talked about suspicious orders. I
17 talked about thresholds.

18 Q. Let me go through, if I
19 could, with you right now the various
20 types of conferences. So there is, as I
21 understand it, a distributor conference
22 that the DEA holds from time to time; is
23 that right?

24 A. Correct.

1 Q. Is it annual or biannual?
2 How often is it typically?

3 A. When I came to headquarters
4 in 2012, we did one in 2013. There
5 was -- there were ones before that.
6 There was a gap. I'm not sure how many
7 years there was a gap. There was a
8 slight gap. We did it in '13, '15, and
9 I'd be guessing, but I know there was at
10 least another one after that.

11 Q. So in the time that you have
12 been at headquarters, they've occurred
13 about every couple of years --

14 A. Correct.

15 Q. -- the distributor
16 conferences?

17 Was there one in '17 that
18 you remember, or sometime after?

19 A. It could be '17. I know it
20 was after the '15.

21 Q. And did you present at the
22 most recent one?

23 A. No. I did the '13 and '15.

24 Q. You presented at the '13 and

1 '15.

2 Now, prior to -- as part of
3 your preparation, did you come to learn
4 of prior distributor conferences that
5 took place?

6 A. Yes. Mm-hmm.

7 Q. Do you recall just
8 approximately what years the other
9 distributor conferences were, just
10 approximately?

11 A. No. The distributor
12 conference became more unique around the
13 time that we did it. But before that it
14 was when they were actually together. It
15 was like an industry conference. And
16 that was -- that was more frequent, I
17 believe. I don't have a time frame for
18 you.

19 Q. And by industry conference,
20 you mean DEA would just attend an
21 industry conference?

22 A. No. It would be a
23 DEA-sponsored conference.

24 Q. So what would be the

1 difference between what you're referring
2 to as the DEA-sponsored industry
3 conference and the distributor
4 conferences that you presented at in 2013
5 and 2015?

6 A. Well, the distributor
7 conference was more directed at the
8 distributors. So the other ones had
9 manufacturers, importers, and wholesalers
10 there.

11 Q. You mentioned -- excuse me.
12 You mentioned that there
13 was -- you were aware that there was a
14 gap in conferences related to
15 distributors. About how long of a gap
16 was there?

17 A. I believe -- I'm not sure.

18 Q. Well, let me --

19 A. I -- go ahead.

20 Q. Let me see if I can jog your
21 memory.

22 I'm aware, and you probably
23 are too, of a distributor conference in
24 2007. Does that ring a bell?

1 A. Yes. Yes.

2 Q. Do you recall Michael Mapes
3 presented at that distributor conference?

4 A. He may have.

5 Q. Between 2007 and 2013, do
6 you recall, based on your preparation,
7 any distributor conferences?

8 A. Not specific to
9 distributors.

10 Q. Were there any industry
11 conferences that were DEA sponsored that
12 encompassed distributors?

13 A. I'm not sure.

14 Q. Sitting here today, based on
15 your preparation and speaking on behalf
16 of the DEA, is the DEA aware of any
17 conference that may have taken place
18 related to distributors between 2007 and
19 2013?

20 A. I believe there were, but
21 I'm not 100 percent positive.

22 Q. Have you seen any
23 documentation of such a conference?

24 A. Not off the top -- I can't

1 recollect right now.

2 Q. You said that there was a
3 several -- or I took it to be a
4 several-year gap between distributor --
5 distributor conferences.

6 What is your understanding
7 as to why there was a gap?

8 A. My under -- I mean, I do
9 know there were distributor initiatives,
10 which is different than a conference.
11 But I do know that there was meetings
12 with distributors about their own data
13 and that kind of thing. So I know that
14 was -- and that went from, so the gap I
15 would say is about 2010 to 2013.

16 Q. And what is your
17 understanding as to why there was a gap
18 at least between 2010 to 2013 as to
19 distributor conferences?

20 A. In my research, it was
21 because we were in -- doing
22 investigations and in litigation against
23 quite a few registrants, particular
24 distributors that communication was a

1 little hard, in -- either in being --
2 either doing the investigation or in the
3 midst of litigation.

4 Q. And I'm sorry to belabor
5 this, but just -- I want to make sure
6 that the record is clear.

7 You're not specifically
8 aware of a distributor conference that
9 took place in 2008, 2009, 2010, are you?

10 MR. FINKELSTEIN: Object to
11 the form.

12 THE WITNESS: At this time
13 I -- I cannot recollect that.

14 BY MS. MAINIGI:

15 Q. So is it possible that there
16 was a gap in distributor conferences that
17 ran essentially from 2008 to 2013?

18 MR. FINKELSTEIN: Objection.
19 Calls for speculation.

20 THE WITNESS: As I said,
21 I -- at this point I can't
22 recollect.

23 BY MS. MAINIGI:

24 Q. So my question was a little

1 bit different, Mr. Prevoznik, is -- my
2 question was, is it possible that there
3 was a gap in distributor conferences that
4 ran essentially from 2008 to 2013?

5 MR. FINKELSTEIN: Objection.
6 Calls for speculation.

7 THE WITNESS: Based on your
8 question, it is possible. But I
9 do know that they -- they -- we
10 were meeting with distributors
11 during that -- some of that
12 period.

13 BY MS. MAINIGI:

14 Q. And in 2008 and 2009 and
15 2010 specifically, you mean there were
16 DEA meetings with distributors?

17 A. Correct.

18 Q. And were those --

19 A. As well as in 2011 with a
20 manufacturer.

21 Q. And -- and were those
22 meetings essentially one-off meetings
23 with particular distributors, to your
24 knowledge?

1 A. What do you mean by one-off?

2 Q. Well for example, there
3 weren't multiple distributors, or
4 representatives of multiple distributors
5 in the room with the DEA.

6 When you were meeting in
7 '08, '09, and '10, it was a meeting with
8 one distributor, correct?

9 A. One distributor that may
10 have a number of different registrations.
11 Not one registration -- it could be one
12 registration. But most distributors have
13 more than one.

14 Q. But you were not -- and did
15 you impart guidance at those meetings in
16 '08, '09 and '10?

17 A. Me personally?

18 Q. The DEA.

19 A. Yes.

20 Q. And -- yes.

21 A. Yes.

22 Q. And I -- I apologize, let me
23 just interrupt what we're going for a
24 second.

1 You are here primarily as
2 the DEA, which I realize can make things
3 a bit artificial.

4 Unless I say otherwise, when
5 I say you, or the DEA, or the
6 administration, I'm generally referring
7 to the entity that is the Drug
8 Enforcement Administration.

9 A. Okay. Thank you.

10 Q. So with respect to policies
11 that were imparted at these individual
12 meetings, could you describe the types of
13 topics that were covered by these
14 policies at these meetings?

15 A. Well, I went over their
16 requirements. Went over the statute,
17 went over the requirements within the
18 C.F.R. Records and reports.

19 Went over -- in particular,
20 we went over 1301.74 about their -- the
21 registrants responsibilities to design
22 and operate a system that could detect
23 suspicious orders, and that they were to
24 notify us upon discovery.

1 Q. Were these meetings in '08,
2 '09 and '10 continuing meetings as part
3 of the distributor initiative?

4 A. Yes.

5 Q. And how long would you say
6 that the distributor initiative lasted,
7 when did it end?

8 A. Oh, it hasn't ended.

9 Q. It's ongoing?

10 A. Yes.

11 Q. And in the context of -- of
12 the multiyear distributor initiative,
13 were you meeting with the same
14 distributors multiple times sometimes?

15 A. No, I don't -- no. I -- it
16 was -- it was different distributors, so
17 that we -- we were meeting with -- we
18 were trying to meet with each one of them
19 so that we can go over their own
20 material, their own data that they had
21 provided us.

22 Q. So one of the functions of
23 the distributor initiative was to go over
24 the data that had been provided by that

1 distributor through ARCOS as well as
2 SORs?

3 A. Definitely ARCOS and we went
4 over the requirements for suspicious
5 orders. I mean, the -- the focus was to
6 show their own data and the abnormalities
7 that their data was showing, and to
8 remind them of suspicious orders. That's
9 why we had litigation and settlements,
10 because they weren't being reported.

11 And I do know that some --
12 some of it we are circling back on some
13 of the registrants with more, you know,
14 meeting again with the -- through the
15 distributor initiative.

16 Q. So when -- when you showed
17 distributors data at some of these
18 distributor initiative meetings, you
19 identified aberrations in the data that
20 you pointed out to the distributors?

21 A. Correct.

22 Q. And were those aberrations
23 that the DEA had followed up on in -- in
24 some manner previously?

1 MR. FINKELSTEIN: Objection.

2 Vague.

3 THE WITNESS: Could you give
4 me a little more guidance on what
5 you mean by followed up with?

6 BY MS. MAINIGI:

7 Q. So -- so generally when the
8 DEA sees an aberration in -- in the data,
9 does the DEA follow up?

10 MR. FINKELSTEIN: Objection.

11 Vague.

12 THE WITNESS: I mean, we --
13 we open investigations on some of
14 the customers. We open
15 investigations on some of the
16 distributors that said they were
17 going to fix it and didn't fix it.
18 So...

19 BY MS. MAINIGI:

20 Q. So the answer is yes, if you
21 see aberrations in the data, the DEA does
22 tend to follow up?

23 A. Correct. Correct.

24 MR. FINKELSTEIN: Object to

1 the characterization.

2 THE WITNESS: I'm sorry.

3 MR. FINKELSTEIN: Wait for
4 me to object.

5 THE WITNESS: Okay.

6 BY MS. MAINIGI:

7 Q. With respect to the
8 distributor initiative, is it fair to say
9 the early years of the distributor
10 initiative, the individuals that attended
11 the distributor meetings were Kyle Wright
12 and Michael Mapes?

13 A. Yes.

14 MS. SINGER: Objection.

15 Lack of foundation.

16 BY MS. MAINIGI:

17 Q. And then in -- who were the
18 individuals from the DEA that were
19 primarily attending the distributor
20 briefings in the '08, '09, and '10 time
21 period?

22 A. It would still be Kyle, Kyle
23 Wright. Lisa Sullivan. Dave White. And
24 then Lenny Levin. Lenny Levin.

1 Q. In that time period, you
2 were still in the field offices or
3 training, so you would not have attended
4 any of the distributor briefings
5 personally --

6 A. Correct.

7 Q. -- Mr. Prevoznik?

8 A. Correct.

9 Q. Why don't we finish out your
10 experience, and then we'll take a short
11 break. Is that okay?

12 A. Sure.

13 Q. With respect to conferences,
14 just to close the loop on those, and we
15 may have further questioning on this,
16 were there -- you mentioned there was a
17 Pharma conference in 2011?

18 A. I didn't --

19 Q. Or for the pharmaceutical
20 industry? I could have that wrong. Was
21 there a separate conference for
22 pharmaceutical manufacturers?

23 A. There was -- the distributor
24 conference came later, but there was an

1 industry conference in which we brought
2 manufacturers, distributors, importers,
3 together.

4 Q. And was there any conference
5 that included just -- well, when was the
6 first year there was a conference just
7 for manufacturers?

8 A. Well, we've always had like
9 a side -- like ARCOS quotas because
10 that -- quotas really pertains to the
11 manufacturers. So we would meet with --
12 it's like a side training, which was done
13 by our quota unit, as well as the ARCOS
14 unit would be there to go over stuff with
15 them as well.

16 I mean, that -- that's --
17 that was going on for a while.

18 Again, we had that little
19 hiatus where, because of the litigation
20 and things that were going on, it was
21 decided not to hold it. And then we
22 brought them back. So they've been
23 meeting, it's usually two places a year.
24 We try to do east coast, west coast or

1 something like that, so we can get as
2 many registrants that have those
3 questions.

4 Q. And that's primarily for
5 registrants that are manufacturers?

6 A. Yeah, manufacturers or
7 importers, but, yeah.

8 Q. And so the -- the ARCOS
9 quotas sessions that you're referencing,
10 do you know what years those took place?

11 MR. FINKELSTEIN: Object to
12 the scope.

13 You can answer if you know.

14 THE WITNESS: I don't know
15 off the top of my head. We do
16 post all our meetings on -- those
17 types of conferences on our DEA
18 diversion website. So if you went
19 to the past meetings, all of that
20 would be there.

21 BY MS. MAINIGI:

22 Q. What about for pharmacies?
23 Is there a separate conference that takes
24 place for pharmacies?

1 A. In 2010 -- no, in 2000 --
2 I'm trying to remember the first one. It
3 was in -- it was in Ohio. We started
4 what we called the pharmacy diversion
5 awareness conference. And the goal was
6 to hit all 50 states, and we did that.
7 And we met with pharmacists, pharmacy
8 techs in all the states and provided
9 continuing education credits for
10 pharmacists and techs.

11 Q. And so there are periodic
12 conferences that occur just for
13 pharmacies put on by the DEA now?

14 A. Well, that was what we did
15 at headquarters. I know that we also go
16 to the associations for pharmacists. I
17 mean, within the field divisions, they do
18 their own conferences with pharmacists.
19 So, I mean, we're out there.

20 Q. Okay. Now, prior to you
21 joining the liaison unit in 2014, you
22 served for a couple of years in the role
23 of diversion staff coordinator.

24 How did that role intersect

1 with suspicious order monitoring and
2 reporting?

3 A. I was in -- I was a staff
4 coordinator in the liaison section. So
5 all I did was -- it's a -- not really a
6 promotion. You're at the same grade
7 level, but you just get a title. You're
8 supervising people of your same --

9 Q. So your responsibilities
10 from May 2012 forward were the same as
11 you just described?

12 A. Yeah.

13 Q. Prior to that time, you were
14 diversion group supervisor in New Jersey
15 and diversion investigator in New Jersey?

16 A. Correct.

17 Q. Can you describe at a high
18 level what your responsibilities were?

19 A. For which one?

20 Q. For both of those. I'm
21 sorry. If they are -- obviously --

22 A. Well, I mean, as a
23 supervisor you are in charge of the
24 group -- I'm sorry.

1 MR. FINKELSTEIN: Hang on.

2 Let her finish.

3 MS. MAINIGI: Sorry, my
4 fault.

5 THE WITNESS: I apologize.

6 No, it's my fault.

7 BY MS. MAINIGI:

8 Q. Why don't we start with
9 diversion investigator. Describe for us
10 what a diversion investigator does
11 generally.

12 A. Okay. So as a diversion
13 investigator, we conduct -- we conduct
14 investigations, whether it's scheduled
15 investigations, where we're out at the
16 registrants' facilities. It's doing
17 administrative investigations, civil
18 investigations, criminal investigations,
19 compliant investigations.

20 It's answering questions of
21 the public. It's answering questions of
22 the registrants at times. It runs the
23 full gamut of what the whole program is
24 about.

1 Q. You were a -- you were also
2 a diversion investigator from
3 February '91 to September of 2001,
4 correct?

5 A. Correct.

6 Q. And was your role from
7 February '91 to September 2001 the same
8 as you have generally described it from
9 when you were a diversion investigator in
10 2006 to 2008?

11 A. Correct.

12 Q. Now, for part of that time
13 period, as a diversion investigator, did
14 you receive and review excessive purchase
15 reports?

16 A. Excessive purchase reports?

17 Q. Yes.

18 A. Yes.

19 Q. And describe for me what an
20 excessive purchase report is.

21 A. An excessive purchase
22 report, it's an after -- it's a
23 transaction that has already occurred.
24 So it's sales data that it -- that was

1 provided by the registrants. So we would
2 review it when it came in.

3 Again, we would separate it
4 by AORs. If -- you know, if I'm in
5 Philadelphia, and I had stuff in New
6 Jersey, I would separate and send New
7 Jersey theirs. And if we had Pittsburgh
8 stuff we would send Pittsburgh their
9 stuff. Maryland got their stuff. So we
10 would review that.

11 Q. And the excessive purchase
12 reports were coming in primarily from
13 distributors?

14 A. Yeah, primarily.

15 Q. And did you -- and so you
16 investigated excessive purchase reports
17 when they came in?

18 A. Yeah, we would review them.
19 And then we would take action if we
20 deemed it necessary.

21 Q. Now, you stopped being --
22 let's see. You stopped being a diversion
23 investigator in December 2008, correct?

24 A. Well, I didn't really stop

1 being one. I still --

2 Q. You're always a diversion
3 investigator?

4 A. Yes, I've been one for
5 28 years.

6 Q. Okay. Your primary
7 responsibilities, you were no longer
8 primarily operating as a diversion
9 investigator after December 2008, fair?

10 A. When I became the
11 supervisor?

12 Q. Yes. As a supervisor, did
13 you continue to function as a diversion
14 investigator as a primary part of what
15 you were doing?

16 A. Not as primary.

17 Q. But sometimes as a
18 general -- in terms of the supervision of
19 investigators, you would provide advice
20 and guidance on what they ought to do?

21 A. Correct.

22 Q. Okay. Is it fair to say
23 that the excessive purchase reports
24 continued to be received by field offices

1 till some time in the 2008 time period?

2 MS. SINGER: Objection.

3 Foundation.

4 THE WITNESS: Can you please
5 repeat the question?

6 BY MS. MAINIGI:

7 Q. Sure. I'll just read it
8 back.

9 Is it fair to say that the
10 excessive purchase reports continued to
11 be received by field offices till
12 sometime in the 2008 time period?

13 A. Yeah. We would still get
14 them.

15 Q. And in that time period,
16 just as in the earlier years, the
17 diversion investigators would continue to
18 investigate the excessive purchase
19 reports?

20 MR. FINKELSTEIN: Objection
21 to the scope.

22 THE WITNESS: So we would --
23 we would review them, again
24 separate by AORs, or we would

1 review them to take whatever
2 action we deem necessary at that
3 point.

4 BY MS. MAINIGI:

5 Q. And separate by AOR, can you
6 describe what that means?

7 A. Area of responsibility.
8 Again, New Jersey is New Jersey.
9 Pennsylvania is Pennsylvania. And then
10 within each state is a different office.

11 Q. And then you spent some time
12 also -- we may come back to the diversion
13 investigator role, Mr. Prevoznik. But
14 let me jump over to the work that you did
15 training.

16 What areas did you train in,
17 was it primarily diversion control?

18 A. It was all diversion
19 control.

20 Q. All diversion control?

21 A. Yeah, I mean I would assist
22 with some of the special agent stuff,
23 but...

24 Q. How much training do

1 diversion investigators as a general
2 matter get?

3 MS. SINGER: Objection.
4 Scope.

5 THE WITNESS: It's 12 weeks.
6 The training at Quantico.

7 BY MS. MAINIGI:

8 Q. All on diversion control?

9 A. Correct.

10 Q. And what are the components
11 of that training at a high level?

12 MS. SINGER: Objection to
13 scope.

14 MR. FINKELSTEIN: I'll join
15 that objection.

16 THE WITNESS: So it would be
17 the -- the law, we would have law.
18 You would have the record
19 requirements. It would be
20 interviewing. It would be audits.
21 Like reviewing records for
22 pharmacy audit. Reviewing records
23 for distributor audit. Reviewing
24 records for a manufacturing audit.

1 Ethics training. Just a lot of
2 interviewing, practicals. We did
3 various practicals as well, just
4 to give them like a real life --
5 try to give them a real life
6 experience as best we could.

7 BY MS. MAINIGI:

8 Q. And after the initial
9 12-week training, are there any refresher
10 courses that are -- or refresher training
11 that is provided to diversion
12 investigators?

13 A. Yes, there is --

14 Q. How often is that?

15 A. It depends. Each -- it --
16 it's typically within three to
17 five years.

18 Q. And how long is the
19 refresher training?

20 A. I believe it was about a
21 week.

22 MS. MAINIGI: Okay. Why
23 don't we go ahead and take a short
24 break. Thank you.

1 THE VIDEOGRAPHER: It's
2 10:30. We are off the video
3 record.

4 (Short break.)

5 THE VIDEOGRAPHER: 10:47.
6 We are on the video record.

7 BY MS. MAINIGI:

8 Q. Mr. Prevoznik, what does the
9 registrant mean in DEA parlance?

10 A. The registrant?

11 Q. What is the meaning of that
12 word?

13 A. A registrant is authorized
14 to handle controlled substances for
15 whichever schedules that their state
16 authority allows them to.

17 Q. And the registrant's
18 responsibility to identify and report
19 suspicious orders is established by
20 regulation, correct?

21 A. By statute.

22 Q. By statute. And do you
23 recall the statute?

24 A. 823.

1 Q. And also relevant is
2 21 C.F.R. 1301.74?

3 A. Correct.

4 Q. The statute and the
5 regulation, do you know how long they
6 have been in place?

7 A. Since it was enacted.

8 Q. Which is when approximately?

9 A. 1971, I think.

10 Q. And have either the statute
11 or regulation been amended or altered
12 since 1971 to your knowledge?

13 A. No, they have not.

14 Q. Now, before the break we
15 discussed excessive purchase reports. Do
16 you recall that?

17 A. Yes.

18 Q. Can you define for me an
19 excessive purchase report?

20 A. Well, again, an excessive
21 purchase report is after the sale has
22 been consummated. So it would be -- I
23 mean, we've seen -- it basically looks
24 like sales of -- of this is what happened

1 for this month or this is what happened
2 for this quarter. We would -- we would
3 see that.

4 Q. To be clear, the excessive
5 purchase reports were not all sales that
6 a particular company had, right?

7 A. It -- it came in various
8 forms and sizes. So sometimes it -- it
9 was all sales. Sometimes it was partial
10 sales. It was -- it was whatever the
11 registrant sent -- sent us.

12 Q. Is it fair to say that at
13 least some of the reports that were
14 received were reports of sales that were
15 over a certain benchmark or threshold,
16 hence the name excessive purchase
17 reports?

18 A. Well, it would depend on
19 what we received. And it's -- it was
20 incumbent upon the registrant to identify
21 if they had thresholds. It was -- if
22 that was their system to do it, it was
23 incumbent upon the registrant.

24 Q. So if a registrant set a

1 certain threshold over which it would
2 report particular sales to the DEA, the
3 DEA wanted to obviously see what that
4 threshold was?

5 A. Well, I guess I'm getting a
6 little confused on your use of the term
7 of "thresholds," because what -- what the
8 requirement of the statute and the law
9 and -- and the regulations is, is to
10 design and operate a system that can
11 detect suspicious orders, which is
12 different than excessive purchases.
13 So...

14 Q. I'm not sure -- let me
15 interrupt you, but I don't think you're
16 answering my question --

17 MR. FINKELSTEIN: No, no.
18 Don't -- don't interrupt the
19 witness. Let the witness finish
20 his answer and -- and you can
21 clarify if you'd like.

22 BY MS. MAINIGI:

23 Q. You can go ahead and finish
24 your answer. But I will let you know

1 that I'm just going to have to re-ask the
2 same question, because I -- I think
3 you're going off on a tangent. Go -- go
4 ahead and --

5 MR. FINKELSTEIN:

6 Mr. Prevoznik, were you -- were
7 you done with your answer?

8 THE WITNESS: Could I --
9 could you repeat what I --

10 BY MS. MAINIGI:

11 Q. Let me withdraw the
12 question, and I will ask a different
13 question.

14 Excessive purchase reports
15 were, as you testified earlier, were
16 received through about the 2008 time
17 period, by the DEA, correct?

18 A. No. Not -- not just --
19 from -- just in 2008? No, it was
20 previous to that.

21 Q. No, through -- yes, I'm
22 sorry --

23 MR. FINKELSTEIN: Let the
24 witness finish his answer.

1 BY MS. MAINIGI:

2 Q. So -- well, let me -- let me
3 ask it this -- when do you recall the DEA
4 first began receiving excessive purchase
5 reports?

6 A. I remember them when I first
7 got into Philadelphia in 1991.

8 Q. And were excessive purchase
9 reports -- well, excessive purchase
10 reports were not always called excessive
11 purchase reports. Different distributors
12 may have called them different things; is
13 that correct?

14 A. I -- I knew them as
15 excessive purchase reports.

16 Q. And did they usually come in
17 paper form or electronically; in what
18 form did they come?

19 A. Could you give me a time
20 period?

21 Q. Sure. Let's deal with the
22 1990s first.

23 A. It was primarily paper.
24 Snail mailed.

1 Q. And what's your recollection
2 as to when approximately they began
3 evolving into electronic?

4 A. I mean, to the field it was
5 always faxes, it was -- it was paper.
6 That -- that's how it came in.

7 So 2008 was when we had our
8 first MOAs with the registrants that --
9 that had an action taken against them.
10 So that was when we said you will file
11 electronically with us here at
12 headquarters.

13 Q. And the form of what got
14 filed with headquarters in that time
15 period also changed, correct?

16 A. The --

17 MR. FINKELSTEIN: Object to
18 the characterization.

19 THE WITNESS: The form of?

20 BY MS. MAINIGI:

21 Q. You said as part of the MOAs
22 in 2008 there was a requirement in some
23 cases to file electronically, correct?

24 A. Yes.

1 Q. The form of what got filed
2 electronically in -- in those cases also
3 changed; is that right?

4 A. Changed in what way?

5 Q. Well, the -- perhaps the
6 reports changed to suspicious order
7 reports; is that right?

8 MR. FINKELSTEIN: Objection:
9 Object to the form.

10 THE WITNESS: They were
11 always required to report
12 suspicious orders. I mean, that's
13 been in the law and the
14 regulations from the beginning, as
15 we discussed when we first came
16 back from break. So I'm not
17 really sure what you're asking.

18 BY MS. MAINIGI:

19 Q. Well, the excessive purchase
20 reports that were received by the DEA
21 field offices, was something that was
22 done by essentially most of the
23 distributors in the industry. Is that
24 fair?

1 A. It's hard to characterize,
2 like, all distributors. The ones that
3 sent them, sent them. You know, I can't
4 say whether or not every single one sent
5 them.

6 Q. Do you recall -- do you
7 recall distributors sending anything
8 other than something called an excessive
9 purchase report or something that looked
10 like an excessive purchase report in the
11 1990s?

12 A. I know that in my review of
13 some of the correspondence that we
14 received, that there were suspicious
15 orders, where in fact the distributors
16 said where we looked at the pattern and
17 we cut off some -- some registrant --
18 registrants that were not in compliance.
19 So we did get some suspicious orders.

20 Q. Let me ask -- let's go ahead
21 and mark this.

22 (Document marked for
23 identification as Exhibit
24 DEA-Prevoznik-4.)

1 BY MS. MAINIGI:

2 Q. I have put in front of you,
3 Mr. Prevoznik, the report to the U.S.
4 Attorney General by the suspicious orders
5 task force. And it's dated October 1998.
6 Do you see that?

7 A. Correct.

8 Q. Did you review this document
9 in preparation for your deposition today?

10 A. I reviewed part of it.

11 Q. Which part did you review?

12 A. Basically -- basically
13 the -- what they were describing as the
14 system that they were going to look to
15 implement.

16 MR. FARRELL: Excuse me.

17 Can you tell me the exhibit number
18 again.

19 MS. MAINIGI: Exhibit 4.

20 BY MS. MAINIGI:

21 Q. "They" being the DEA?

22 A. Well, it was -- it was part
23 of the -- Comprehensive Methamph- --
24 Control Act task force between the DEA

1 and the registrant community, get
2 together to talk about putting together a
3 suspicious order system for chemicals.
4 So that's what this was. This was a
5 requirement by the Act for us to sit down
6 and come up with a monitoring system.

7 Q. And so DEA officials
8 participated in the task force, correct?

9 A. Correct.

10 Q. If you take a look at the
11 bottom there, where there are some
12 numbers, and look at 2283.

13 A. I'm sorry. I'm losing you.
14 Okay, I got you.

15 Q. So at 2283 forward, there is
16 the membership of the suspicious orders
17 task force, correct?

18 A. Correct.

19 Q. And the chairman is from the
20 DEA office of diversion control; is that
21 right?

22 A. Correct.

23 Q. And then it looks like there
24 are also various DEA employees from

1 various field offices; is that fair?

2 A. Other than Page 2283?

3 Q. Yes. You can feel free to
4 look at other pages.

5 A. I just see the ones on 2283.

6 Q. And who are the other ones
7 on 2283.

8 A. David Walkup, and Edward Van
9 Patten.

10 Q. And so Mr. Walkup was from
11 the DEA St. Louis division, correct?

12 A. Correct.

13 Q. And then Mr. Van Patten was
14 from the DEA Sacramento office, correct?

15 A. Correct.

16 Q. As you were, I think,
17 alluding to earlier, the purpose of this
18 task force primarily was to provide
19 recommendations for suspicious order
20 reporting of List 1 chemicals; is that
21 right?

22 A. Correct.

23 Q. And List 1 chemicals are
24 different from controlled substances like

1 prescription opioids, right?

2 A. Yes.

3 Q. Take a look at Page 2230,
4 please. Now, did you read this part of
5 the report when you prepared before?

6 A. Yes.

7 Q. If you want to just take a
8 moment and just make sure you're familiar
9 with it again.

10 A. Okay.

11 Q. Now, one of the things that
12 this task force did in this report was to
13 provide recommendations to various parts
14 of the supply chain, correct?

15 A. Correct.

16 Q. And the page we're looking
17 at, 2230, are some recommendations to
18 wholesale distributors, correct?

19 A. Correct.

20 Q. Now, if we take a look at
21 B1. Could you read out loud the first
22 sentence.

23 A. "That those in the wholesale
24 drug distribution supply chain who are

1 able" -- "who are able use the
2 DEA-approved suspicious order monitoring
3 system in use by wholesale drug
4 distributors for controlled substances as
5 enhanced by the task force in Appendix A,
6 Exhibit 2, for the reporting of
7 potentially suspicious orders of listed
8 chemicals, including ephedrine,
9 pseudoephedrine, and
10 phenylpropanolamine."

11 Q. In developing its
12 recommendations, it appears that the task
13 force considered systems that registrants
14 were already using to report suspicious
15 orders of controlled substances, correct?

16 A. Yes.

17 Q. And as we saw from the
18 members of the task force, the DEA was
19 involved in developing these
20 recommendations and preparing this
21 report, correct?

22 A. Correct.

23 Q. The reference to the
24 DEA-approved suspicious order monitoring

1 system in use by wholesale drug
2 distributors for controlled substances,
3 do you see that reference that you just
4 read?

5 A. Yes.

6 Q. Is it fair to say then,
7 there was in fact at this point in time,
8 in 1998, a DEA-approved suspicious order
9 monitoring system for controlled
10 substances?

11 A. I would say no, because
12 there was never a -- DEA never had an
13 approved system. The system that the
14 statute requires and the regulations
15 require is the registrant is to design
16 and operate that system.

17 They come to us and they
18 say, here's our system, and we may have
19 discussions with them about it. So you
20 can have a great system in paper, but
21 when you implement it, are you actually
22 implementing what you say.

23 So that's part of our job,
24 when we go out there for schedule

1 investigation, is to look at that program
2 and are they doing what they're saying,
3 is it actually detecting suspicious
4 orders.

5 Q. So, Mr. Prevoznik, try to
6 listen to my question and answer it. I
7 realize that you would like to speechify
8 a little bit and get out your talking
9 points, but please restrain --

10 MR. FINKELSTEIN: Try not to
11 argue with the witness.

12 BY MS. MAINIGI:

13 Q. -- from doing that.

14 MR. FINKELSTEIN: You can
15 ask your questions. And you're
16 not here to abuse him.

17 BY MS. MAINIGI:

18 Q. So, Mr. Prevoznik, let's
19 back up. The DEA helped to write this
20 report, right?

21 A. Correct.

22 Q. And someone from the office
23 of diversion control at the DEA was in
24 fact the chair of the group that wrote

1 this report, correct?

2 A. Correct.

3 Q. The terminology that they
4 used in 1998 referenced a DEA-approved
5 suspicious order monitoring system in use
6 by drug distributors for controlled
7 substances, right? That's what the
8 report references?

9 A. Correct.

10 Q. Are you aware in all of the
11 work that you did, any sort of amendment
12 to this report that came out that perhaps
13 we may not have been privy to that
14 changed this language we've been
15 referring to that says "DEA-approved
16 suspicious order monitoring system for
17 controlled substances"?

18 MR. FINKELSTEIN: Objection.
19 Vague.

20 THE WITNESS: No, I am not
21 aware of any.

22 BY MS. MAINIGI:

23 Q. Did you personally know any
24 of the individuals from the DEA involved

1 in putting this report together?

2 A. Yes.

3 Q. Who was that?

4 A. I knew Bill Wolf and I knew
5 Dave Walkup.

6 Q. Did you read this report
7 when it came out?

8 A. I don't recall.

9 Q. In the field would you have
10 been privy to reading this report?

11 A. What do you mean privy to
12 it?

13 Q. Would you have received
14 it --

15 A. Like they hand it to us?

16 Q. I'm sorry.

17 Would you have received a
18 copy of this report as a diversion
19 investigator?

20 A. Maybe. It's a
21 recommendation. So I don't -- it would
22 be maybe.

23 Q. Okay. Are you -- do you
24 think Mr. Wolf would just make up that

1 language if it didn't exist?

2 MR. FINKELSTEIN: Objection.

3 Argumentive.

4 THE WITNESS: I -- I

5 don't -- no, I -- no, I know Bill.

6 BY MS. MAINIGI:

7 Q. So at least in Mr. Wolf's
8 mind, there was a DEA approved suspicious
9 order monitoring system for controlled
10 substances, fair?

11 MR. FINKELSTEIN: Objection.

12 Calls for speculation.

13 THE WITNESS: I don't know.

14 BY MS. MAINIGI:

15 Q. To your knowledge, the DEA
16 has never disavowed this task force
17 report, correct?

18 A. Well, I know it never got
19 implemented.

20 Q. Okay. And did the DEA ever
21 write to the task force and say you are
22 completely incorrect about some of these
23 things in here?

24 A. I'm not aware of that.

1 Q. And did you read far enough
2 in the report to see that there was, in
3 fact, an algorithm that was contained as
4 an exhibit to the report?

5 A. Do you have a page number?

6 Q. Sure: Bates Number 2247.

7 Did you review this page
8 previously?

9 A. Yes.

10 Q. Okay. And -- and this page
11 essentially contains a calculation or
12 algorithm for both List I chemicals and
13 Schedule II controlled substances,
14 correct?

15 A. Correct.

16 Q. Now, DEA did not require
17 distributors to use a particular
18 algorithm or metric to identify excessive
19 purchases of controlled substances,
20 correct?

21 A. Could you please repeat
22 that?

23 Q. DEA did not require that a
24 distributor use a particular calculation

1 or algorithm to identify excessive
2 purchases of controlled substances,
3 correct?

4 A. Correct.

5 Q. But, the DEA was aware that
6 certain registrants were using a
7 calculation or metric or algorithm to
8 identify an excessive purchase, correct?

9 MR. FINKELSTEIN: Objection.
10 Vague as to time.

11 THE WITNESS: I -- I just
12 want to make sure I'm clear on
13 this. We're talking about
14 excessive purchases or are we
15 talking about suspicious orders?

16 BY MS. MAINIGI:

17 Q. Well, right now I'm talking
18 about excessive purchase reports in this
19 time period.

20 Was the DEA aware that in
21 approximately the 1998 time period, that
22 distributors were using a particular
23 algorithm or calculation to identify
24 excessive purchases of controlled

1 substances?

2 A. I don't know if they used it
3 for -- to determine excessive purchases.
4 It was -- like, this, this report is
5 about suspicious orders. So that's why
6 I'm a little confused on -- on that. If
7 you could help clarify it.

8 Q. Well, the first -- do you
9 see terms and definitions on this page?

10 A. Mm-hmm.

11 Q. Could you read the first
12 sentence out loud?

13 A. "This formula is used to
14 calculate the quantity which, if exceeded
15 in one month, constitutes an order which
16 may be considered excessive or
17 suspicious."

18 Q. So you see that term and
19 definition does refer to both excessive
20 and suspicious, correct?

21 A. Correct.

22 Q. Okay. So were you aware
23 that certain registrants were using an
24 algorithm or calculation to identify

1 excessive purchases?

2 A. Well, I'm -- I'm going to go
3 with what this says, excessive or
4 suspicious. Because it sounds like they
5 are being used simultaneously. So yes,
6 we were aware.

7 MR. FARRELL: Maybe to save
8 some time, can you clarify whether
9 your questions are pertaining to
10 List I chemicals or controlled
11 substances?

12 MS. MAINIGI: I think the
13 questioning is clear, Paul. If
14 you think it's not, you can
15 clarify it when you do your
16 questioning.

17 MR. FARRELL: Thank you.

18 Can I ask the court reporter
19 to tag this area of the transcript
20 so we can revisit it tomorrow?

21 BY MS. MAINIGI:

22 Q. So continuing to look at
23 Exhibit 2 of the suspicious order task
24 force report from 1998, Mr. Prevoznik, on

1 Page 2247, as you see up top how is the
2 calculation -- how is the calculation
3 described at the top of the page?

4 MR. FINKELSTEIN: Objection.
5 Vague.

6 THE WITNESS: Above terms
7 and definitions --

8 BY MS. MAINIGI:

9 Q. Do you see the --

10 A. -- or below it?

11 Q. Yes. Yes, above.

12 A. The current calculation
13 being used of List I chemicals and
14 Schedule II through V controlled
15 substances.

16 Q. So Schedule II controlled
17 substances includes oxy, correct?

18 A. Correct.

19 Q. And this chart that's an
20 exhibit to this report notes that the
21 below is the current calculation being
22 used for Schedule II substances, correct?

23 MR. FARRELL: Objection.
24 Misstates the document.

1 THE WITNESS: I'm not -- I'm
2 not sure what the calculation --
3 what -- is it -- it could be the
4 ARCOS calculation. I don't
5 really -- I can't tell from this
6 document what the -- what
7 calculation they are applying it
8 to.

9 BY MS. MAINIGI:

10 Q. Well --

11 A. Because --

12 Q. -- it's being applied to, as
13 you read before, an order which may be
14 considered excessive or suspicious,
15 right?

16 A. Yes, that's correct.

17 Q. So is it fair to say that
18 this document that the DEA participated
19 in putting together in 1998, reflects
20 that there was a calculation that was
21 being used for Schedule II controlled
22 substance reporting?

23 MR. FARRELL: Objection.

24 Misstates the document.

1 THE WITNESS: Again, I'm not
2 sure what the calculation --
3 what -- how they're using -- where
4 they got the calculation from. If
5 it's an ARCOS -- an ARCOS
6 calculation, or -- or how they got
7 it. There's nothing on this --
8 this particular sheet that tells
9 me that.

10 BY MS. MAINIGI:

11 Q. Well, you did some due
12 diligence around this time period,
13 correct?

14 A. Correct.

15 Q. And you were personally even
16 aware that, since you were a diversion
17 investigator, that there were excessive
18 order reports that were being sent in
19 periodically by distributors, correct?

20 A. So now it's excessive
21 orders, correct? So suspicious orders?

22 Q. I -- I'm asking you about
23 excessive order reports.

24 A. Well, I'm -- I'm aware that

1 we got excessive purchase reports which
2 are after sales things. We also got
3 reports, suspicious order -- some
4 suspicious order reports as well, which
5 is before the transaction occurs.

6 Chemicals, it was phone
7 calls, it was various forms of
8 information given to us to tell us what
9 those orders were.

10 This -- this is a proposed
11 system, which was never enacted.

12 Q. Well, that's -- that's where
13 we're having --

14 MR. FINKELSTEIN: Hey.

15 That -- that's, I'll note for the
16 record, the fourth time you've
17 interrupted the witness's answer.
18 I'll ask again nicely to please
19 let the witness finish his
20 answers.

21 MS. MAINIGI: I think I did
22 let him finish his answer.

23 BY MS. MAINIGI:

24 Q. In case I didn't,

1 Mr. Prevoznik, I apologize.

2 I think what we just went
3 over is the fact that there is a current
4 calculation still in place for
5 Schedule II controlled substances, right?

6 MR. FARRELL: Objection.

7 Misstates the testimony and
8 misstates the document.

9 THE WITNESS: Again, I --
10 I -- again, I don't know where
11 the -- what the calculation is.
12 Is it from ARCOS? Is it from --
13 is this a algorithm that the
14 industry has in place? I'm not
15 really sure where the algorithm
16 came from. So it's hard for me to
17 answer that question without
18 knowing where that came from.

19 BY MS. MAINIGI:

20 Q. Well, it says up top "For
21 use in automated tracking systems,"
22 right?

23 A. Right. Which goes back to
24 what the statute and the regulations say,

1 is that the registrant is to design and
2 operate the system. So I don't know if
3 this is a system that the industry did or
4 are they using a calculation based off of
5 ARCOS, because there's calculations that
6 are based off of ARCOS.

7 Q. The DEA today does not
8 necessarily endorse or bless a particular
9 system for suspicious order reporting,
10 correct?

11 A. Correct.

12 Q. The DEA goes out of its way
13 to not provide guidance as to what should
14 or should not be contained in a system
15 for suspicious order reporting, correct?

16 MR. FINKELSTEIN: Objection.
17 Object to the form.

18 THE WITNESS: No, I would
19 disagree with that.

20 BY MS. MAINIGI:

21 Q. Does the DEA provide
22 guidance as to what a distributor should
23 put into their suspicious order
24 monitoring system?

1 A. I believe we provided quite
2 a bit of -- quite a bit of guidance to
3 the registrant.

4 Q. And on the issue of the
5 suspicious order monitoring system, can
6 you describe where I could find that
7 guidance, what should go into a
8 suspicious order monitoring system?

9 A. Okay. Well, as is the --

10 Q. Just tick them off for me.
11 We'll go back to them later.

12 A. Well, I just want to go
13 through the regulations because --

14 Q. The regulations. Okay.
15 What's next?

16 A. We gave guidance in 2006 to
17 "Dear Registrant." And then in 2007.
18 We've given guidance at the distributor
19 initiatives of various topics that should
20 be looked at.

21 We've given it at
22 conferences. We've given it through
23 policy letters.

24 Q. What policy letters?

1 A. 2006.

2 Q. The same ones that you just
3 talked about?

4 A. Yeah.

5 Q. The "Dear Registrant"
6 letters?

7 A. Yes.

8 Q. Do you have policy letters
9 besides the Joe Rannazzisi 2006, 2007
10 letters?

11 A. I don't particularly have
12 them with me.

13 Q. Are you aware of them?

14 A. There were some letters sent
15 in, specific from registrants to our
16 policy section.

17 Q. That went to the entire
18 industry?

19 A. No.

20 Q. So can something be a policy
21 letter if it's just sent to one entity?

22 MR. FINKELSTEIN: Objection.

23 Calls for a legal conclusion.

24 THE WITNESS: I don't --

1 BY MS. MAINIGI:

2 Q. Okay. So the guidance --
3 just to be clear, the guidance that you
4 are recalling right now related to how a
5 suspicious order monitoring system should
6 be put together, is the following: The
7 regulation, the Rannazzisi 2006, 2007
8 letters, what was said at distributor
9 initiatives and conferences. Anything
10 else?

11 A. I'm aware of guidance from,
12 like, national associations.

13 Q. Was that guidance endorsed
14 by the DEA?

15 A. I know NABP, we reviewed it,
16 the red flags.

17 The -- I think that's it off
18 the top.

19 Q. So NABP red flags, was there
20 an endorsement of those red flags by the
21 DEA?

22 A. We reviewed it. We were
23 listed on the document.

24 Q. Is that an endorsement?

1 A. What do you mean in terms of
2 endorsement?

3 Q. Did you put that out to the
4 industry as red flags that the DEA says
5 the industry should be aware of?

6 A. Well, it was more than just
7 DEA -- it was more than just NABP. It
8 was the industry helped write them. So
9 it was associations. It was a couple
10 manufacturers, a couple wholesalers,
11 various associations. So it was more
12 than just DEA and NABP. It was the
13 industry trying to address the opioid
14 crisis.

15 Q. Now, as you've described,
16 did the -- the DEA understood that the
17 excessive purchase reports listed orders
18 that had already been shipped, correct?

19 A. Correct.

20 Q. And you referenced the
21 Rannazzisi letters just a moment ago, so
22 I take it you're familiar with those
23 letters?

24 A. Yes.

1 Q. Okay. And are you familiar
2 with the fact that the December 2007
3 Rannazzisi letter advised the industry
4 that they should no longer submit
5 excessive order reports?

6 A. Yes.

7 Q. Prior to 2007, did the
8 administration, the DEA administration,
9 issue any guidance to the industry
10 stating that excessive order reports
11 should not be submitted?

12 A. I am not aware of any.

13 Q. Is it fair to say that the
14 submission of excessive purchase reports
15 was an accepted practice until about the
16 2008 time period?

17 MR. FINKELSTEIN: Objection.
18 Vague.

19 THE WITNESS: Could you
20 please repeat it?

21 BY MS. MAINIGI:

22 Q. Is it fair to say that the
23 submission of excessive purchase reports
24 was an accepted practice until about the

1 2008 time period?

2 MR. FINKELSTEIN: Same
3 objection.

4 THE WITNESS: I mean, if the
5 registrant wanted to send them in,
6 they sent them in, so...

7 What we were trying -- what
8 we were trying -- what we were
9 saying is that the suspicious
10 order, you need to look at it
11 before it gets shipped. So we
12 were reiterating what's in the
13 regulations and in the statute,
14 the effective controls guarding
15 against diversion. So that's what
16 we were doing.

17 BY MS. MAINIGI:

18 Q. And to be clear, that's what
19 you were doing in 2007 when the
20 December 2007 letter said, no more
21 excessive order reports, correct?

22 MR. FINKELSTEIN: Object to
23 the characterization of the
24 letter.

1 THE WITNESS: Could you
2 please repeat it?

3 BY MS. MAINIGI:

4 Q. And to be clear, that's what
5 you were doing in 2007 when the
6 December 2007 letter said, no more
7 excessive order reports?

8 MR. FINKELSTEIN: Same
9 objection.

10 THE WITNESS: Yes.

11 BY MS. MAINIGI:

12 Q. Is it fair to say that the
13 DEA understood that excessive order
14 reports were being submitted by some
15 registrants consistent with their
16 obligations under the law?

17 MR. FINKELSTEIN: Objection.
18 Vague.

19 THE WITNESS: I don't -- I
20 don't -- I can't answer what was
21 in the mind of the registrants for
22 doing that.

23 BY MS. MAINIGI:

24 Q. Let me repeat the question.

1 Is it fair to say that the
2 DEA understood that excessive order
3 reports were being submitted by
4 registrants in order to comply with their
5 obligations under the law?

6 MR. FARRELL: Objection.
7 Foundation.

8 MR. FINKELSTEIN: Objection.
9 Vague. Calls for speculation.

10 THE WITNESS: I would say --
11 I would say that's not fair,
12 because we did keep -- through the
13 years, we have underscored the
14 fact that the regulation requires
15 upon discovery a suspicious order,
16 which is not to be -- it's
17 after -- it's before the purchase.

18 So we have been consistent
19 on that, that the industry needs
20 to identify these suspicious
21 orders upon discovery, and they're
22 supposed to tell us.

23 BY MS. MAINIGI:

24 Q. Prior to the -- I think

1 we've already determined that prior to
2 December of 2007, you're not aware of the
3 DEA saying to the industry, no more
4 excessive purchase reports, right?

5 MR. FINKELSTEIN: Object to
6 the characterization of the
7 witness's testimony.

8 THE WITNESS: I would say
9 if -- we would take any data that
10 anybody wants to give us, so...

11 BY MS. MAINIGI:

12 Q. That didn't answer my
13 question.

14 A. I'm sorry.

15 MR. FINKELSTEIN: Objection.
16 Argumentive.

17 BY MS. MAINIGI:

18 Q. We've already established
19 that prior to 2007 you're not aware of
20 the DEA saying, no more excessive
21 purchase reports, right?

22 A. Right. Correct.

23 MR. FINKELSTEIN: Let me
24 object.

1 THE WITNESS: Sorry.

2 MR. FINKELSTEIN: Object to
3 the characterization. You can
4 answer.

5 THE WITNESS: Correct.

6 BY MS. MAINIGI:

7 Q. And the DEA was aware that
8 there were, in fact, being routinely
9 submitted by distributors excessive
10 purchase reports on a regular basis,
11 right?

12 A. We were aware.

13 Q. And you were also aware that
14 there were employees of the DEA that had,
15 in fact, blessed certain excessive
16 purchase reporting systems, right?

17 MR. FINKELSTEIN: Objection.

18 MR. FARRELL: Objection.

19 Foundation.

20 THE WITNESS: I'm not aware
21 of employees --

22 BY MS. MAINIGI:

23 Q. This isn't about you, this
24 is the DEA.

1 Was the DEA aware that
2 certain employees had, in fact, blessed
3 the excessive purchase reporting systems?

4 MR. FARRELL: Objection.
5 Foundation.

6 THE WITNESS: I don't know
7 which employees you're speaking
8 of.

9 BY MS. MAINIGI:

10 Q. Just employees. Is -- is it
11 fair to say that the DEA did, in the late
12 '90s and early aughts, from time to time
13 review the reporting systems of
14 distributors and essentially give them a
15 yay or nay as to whether they thought
16 that the reporting system was suspicious?

17 MR. FARRELL: Objection.
18 Foundation.

19 MR. FINKELSTEIN: Objection.
20 Vague.

21 THE WITNESS: You lost me on
22 the last part.

23 BY MS. MAINIGI:

24 Q. Okay. Let me start over.

1 We -- we established before
2 that the DEA today does not review
3 reporting systems, right?

4 MR. FINKELSTEIN: Objection.
5 Mischaracterizes the witness's
6 testimony.

7 THE WITNESS: I mean, we --
8 we reviewed McKesson's, the new
9 one.

10 BY MS. MAINIGI:

11 Q. And you left it --

12 A. -- we reviewed it, we -- we
13 did not -- we --

14 MR. FINKELSTEIN: Let the
15 witness answer the question.

16 THE WITNESS: I don't know
17 what you mean by the term
18 "blessing it."

19 BY MS. MAINIGI:

20 Q. Okay.

21 A. Because as I had said
22 previously, that you -- you can write the
23 best system in the world, but if you
24 don't implement it and you don't stick to

1 it, it doesn't mean anything.

2 So that's part of our
3 review, when we go out and do schedule
4 investigations, is to review, are they
5 factually, in fact -- did -- is -- are
6 they operating a system that can detect a
7 suspicious order.

8 BY MS. MAINIGI:

9 Q. And that's something that
10 the DEA reviews periodically as part of
11 its auditing process, correct?

12 A. Correct.

13 Q. So as part of the audit
14 process, operating systems that are
15 designed to review suspicious orders are
16 reviewed by the DEA?

17 A. Well, it's not just the
18 schedule. I mean it could be a
19 pre-registration, somebody is coming on
20 and they have -- we have to go through
21 the whole public interest of, you know,
22 what do you have in place to operate and
23 detect a system. So it's not just a
24 schedule investigation. There are

1 schedule investigations that we follow
2 up, and we do that as well. So it comes
3 in -- it comes in various times that
4 we're going to review somebody's
5 operating system, whether we're on
6 schedule investigation, or whether we're
7 doing an investigation on a pharmacy or
8 something like that, where we're going to
9 look at how many SORs were submitted or
10 not submitted, or we're going to look at
11 the ARCOS data, how much did they buy.

12 We're going to look at
13 various things to make the determination
14 on what is going on.

15 Q. And if either in the
16 pre-registration process or in the audit
17 process the DEA determines that a
18 registrant's system is not adequately
19 detecting suspicious orders, is that
20 something that is conveyed to the
21 registrant?

22 A. Yeah, we -- we would tell
23 them, you need to add something.

24 Q. It's clear in the Rannazzisi

1 letters that there was a line that the
2 DEA was drawing, that they would not
3 provide formal approval of a particular
4 system for reporting suspicious orders,
5 correct?

6 MR. FINKELSTEIN: I'm just
7 going to note that the letters are
8 not in front of the witness.

9 You can answer if you
10 remember.

11 THE WITNESS: Can I have the
12 letters?

13 BY MS. MAINIGI:

14 Q. I think you have it in your
15 binder, so please feel free to open it
16 up.

17 A. Which -- which letter?

18 Q. It's the December 27, 2007,
19 Rannazzisi letter. Why don't we -- you
20 can look at your copy or the exhibit
21 copy.

22 But why don't we go ahead
23 and just mark it.

24 MR. FINKELSTEIN: You -- you

1 can look at the letter.

2 (Document marked for
3 identification as Exhibit
4 DEA-Prevoznik-5.)

5 THE WITNESS: So --

6 BY MS. MAINIGI:

7 Q. Do you need my question read
8 back?

9 A. Oh, I thought you just said
10 to review it first. I'm sorry -- I'm
11 sorry --

12 Q. Go ahead. I'm sorry.

13 MR. FINKELSTEIN: Let me
14 just say, there's a lot of
15 paperwork. So you -- you can
16 review either copy, that's fine.

17 THE WITNESS: I'll go with
18 what she has, that's fine.

19 MR. FINKELSTEIN: Just don't
20 get confused.

21 MR. FULLER: This is
22 Exhibit 5?

23 MS. MAINIGI: Yes.

24 THE WITNESS: Okay.

1 BY MS. MAINIGI:

2 Q. Exhibit 5 is a December 27,
3 2007, letter written by Joseph Rannazzisi
4 on behalf of the DEA to registrants,
5 correct?

6 A. Correct.

7 Q. And this letter was sent
8 industrywide; is that right?

9 A. Correct.

10 Q. And this is the letter that
11 we were referring to which referenced the
12 concept that excessive purchase reports
13 were no longer acceptable by the DEA,
14 correct?

15 A. Correct.

16 Q. And can you read to me the
17 specific sentence from this letter that
18 states that?

19 A. The one that says, "Filing a
20 monthly report of completed transactions,
21 for example excessive purchase report or
22 high unit purchases, does not meet the
23 regulatory requirement to report
24 suspicious orders"?

1 Q. Yes. The DEA was
2 communicating to the industry that,
3 through this letter, that they did not
4 want to any longer accept excessive
5 purchase reports, correct?

6 MR. FINKELSTEIN: Objection.
7 Mischaracterizes the letter.

8 THE WITNESS: It just says
9 it doesn't meet regulatory
10 requirement. It doesn't say we
11 don't want them.

12 BY MS. MAINIGI:

13 Q. Does this refresh your
14 recollection also, Mr. Prevoznik, that
15 excessive purchase reports were sometimes
16 called other things like high unit
17 purchases, for example?

18 A. Yes.

19 Q. Do you remember any other
20 names given to excessive purchase reports
21 over the years?

22 A. No.

23 Q. But there were other names
24 that different distributors put on those

1 reports, correct?

2 A. Possibly, yes.

3 Q. And in your capacity as a
4 diversion investigator, you actually
5 reviewed excessive purchase reports,
6 correct?

7 A. Yes.

8 Q. Now, prior to this letter,
9 had the agency issued any guidance, any
10 written guidance to the industry in the
11 same manner as they are sending out this
12 December 27, 2007, letter stating that
13 excessive purchase reports did not comply
14 with 21 C.F.R. 1301.74?

15 A. Could you please repeat the
16 question?

17 Q. Prior to December 27th,
18 2007, the date of this Rannazzisi letter,
19 had the agency issued any written
20 guidance to the industry stating that
21 excessive purchase reports did not comply
22 with the requirements the industry had
23 under 21 C.F.R. Section 1301.74?

24 A. I'm not aware.

1 Q. Now, the DEA also says in
2 the last sentence of the second
3 paragraph, "Past communications with DEA,
4 whether implicit or explicit, that could
5 be construed as approval of a particular
6 system for reporting suspicious orders,
7 should no longer be taken to mean that
8 DEA approves a specific system."

9 Do you see that?

10 A. Yes.

11 Q. Does that refresh your
12 recollection that there were past
13 circumstances where it was understood by
14 at least a registrant that the DEA had
15 provided implicit or explicit approval of
16 their system for reporting suspicious
17 orders?

18 MR. FINKELSTEIN: Objection.
19 Argumentive.

20 THE WITNESS: What it
21 refreshes my memory is that --
22 this goes back to whether it was
23 preregistration or a schedule
24 investigation, in which we're

1 explained this is how it's going
2 to operate, so that's where that
3 may -- where they felt that, but
4 we were also explicit that you
5 needed to be -- you needed to
6 identify suspicious orders.

7 BY MS. MAINIGI:

8 Q. Mr. Prevoznik, you have
9 spoken to a lot of people to prepare for
10 this deposition, right?

11 A. Mm-hmm.

12 Q. And you were a diversion
13 investigator in the field for quite a
14 long time, right?

15 A. Yes.

16 Q. And you were a trainer of
17 diversion investigators, right?

18 A. Yes.

19 Q. Are you seriously sitting
20 here and telling me under oath that
21 you're not aware as the DEA in this
22 deposition, that you're not aware that
23 the DEA, from time to time in prior time
24 periods, did implicitly or explicitly

1 provide approval of systems for reporting
2 suspicious orders?

3 MR. FINKELSTEIN: Hang on.
4 Objection. Argumentive. The
5 witness is aware of his oath.
6 Your suggestion to the contrary is
7 unnecessary.

8 MS. MAINIGI: We don't need
9 speaking objections, David.

10 MR. FINKELSTEIN: I'm not
11 done. Your suggestion to the
12 contrary is unnecessary. I'd ask
13 you not to do that --

14 MS. MAINIGI: We don't need
15 speaking objections, David.

16 MR. FINKELSTEIN: I ask you
17 not to do that in the future.

18 And if you understand the
19 question, you can answer.

20 THE WITNESS: Could you
21 please repeat the question?

22 MS. MAINIGI: I'll ask the
23 court reporter to read it back.

24 (Whereupon, the court

1 reporter read back the requested
2 portion of testimony.)

3 THE WITNESS: I don't
4 believe that's what I testified
5 to. I believe what I was
6 trying -- what I was trying to
7 show you is that there are times
8 when we are given the
9 documentation of this is what the
10 operating system would be. We
11 would say, "Fine."

12 So if you want to say that
13 that's implicit or explicit,
14 that's fine.

15 But then there's the other
16 side of it, is when we do the
17 investigations, schedule
18 investigations, whatever
19 investigations we're doing, are we
20 in fact -- are they in fact doing
21 what they said they're doing.

22 So I apologize if you think
23 I'm not answering the question. I
24 think I am answering the question

1 because I don't know what's in the
2 mind of the registrant when DEA
3 looks at their protocol that they
4 have written and we say, "Yeah, it
5 looks good." Because we do do
6 that.

7 But if it's not implemented
8 and they're not following what
9 they are saying, that's when we
10 take action.

11 BY MS. MAINIGI:

12 Q. So, Mr. Prevoznik, let me
13 approach it then a different way,
14 since -- since you do think that there's
15 sometimes may be -- in the past may have
16 been implicit or explicit approval.

17 MR. FINKELSTEIN: Objection.

18 BY MS. MAINIGI:

19 Q. Is it fair to say that in
20 time periods prior to 2008, there were
21 communications that the DEA had with
22 certain registrants, whether implicit or
23 explicit that could be construed as
24 approval of a particular system for

1 reporting suspicious orders?

2 MR. FINKELSTEIN: Objection.

3 You don't have to accept
4 Ms. Mainigi's characterization of
5 your testimony.

6 MS. MAINIGI:

7 Mr. Finkelstein, would you please
8 stop with the coaching and the
9 speaking objections? Otherwise
10 we're going to have to reach out
11 to Special Master Cohen.

12 MR. FINKELSTEIN: I will
13 respond to what you just said.
14 You can ask your questions. I
15 will continue to make my
16 objections, and the witness can
17 answer those questions subject to
18 my objections.

19 THE WITNESS: Could you
20 please repeat it.

21 MS. MAINIGI: Sure. I
22 will -- I will ask the question
23 again.

24 BY MS. MAINIGI:

1 Q. Is it fair to say that in
2 time periods prior to 2008, there were
3 communications that the DEA had with
4 certain registrants, whether implicit or
5 explicit, that could be construed as
6 approval of a particular system for
7 reporting suspicious orders?

8 MR. FINKELSTEIN: I'll note
9 for the record that wasn't the
10 question.

11 But you can answer.

12 THE WITNESS: Yes.

13 BY MS. MAINIGI:

14 Q. And that included systems
15 for reporting excessive purchase reports,
16 correct?

17 MR. FINKELSTEIN: Objection.
18 Vague.

19 THE WITNESS: For excessive
20 purchase reports?

21 BY MS. MAINIGI:

22 Q. Including - that approval
23 included approvals for excessive purchase
24 reporting systems, correct?

1 MR. FINKELSTEIN: Objection.

2 Vague.

3 THE WITNESS: I'm not the --
4 I'm not the registrant. I mean
5 the regs required them to op -- to
6 be able to detect a suspicious
7 order. So the excessive purchases
8 is different than the suspicious
9 order.

10 BY MS. MAINIGI:

11 Q. Are you aware that the DEA
12 did provide implicit or explicit approval
13 of excessive purchase reporting systems
14 of registrants?

15 MR. FINKELSTEIN: Objection.
16 Vague as to time.

17 THE WITNESS: Again, I'm not
18 sure what -- like I said, if -- if
19 the registrant construed it based
20 on us meeting with them and
21 reviewing their system, and we
22 said, "Yeah, looks good," then
23 yes. But it also has to go with
24 the other side of when you go out

1 and look at it, are they doing
2 actually what they said they're
3 doing.

4 BY MS. MAINIGI:

5 Q. You've referenced -- where
6 you seem to be going, Mr. Prevoznik,
7 is -- is many years later, you want to
8 take the position that excessive order
9 reports were submitted, but people should
10 have been looking for suspicious orders
11 too, right? That's the position that you
12 want to take?

13 MR. FINKELSTEIN: Objection
14 to the characterization and
15 argumentative.

16 THE WITNESS: I don't think
17 that's what -- the angle that I'm
18 going with. I'm trying to tell
19 you that from the very beginning,
20 we both went through the statute
21 and agreed that the regs have not
22 changed since this began.

23 So the regs are very clear
24 on the -- the statute is clear on

1 maintaining -- guarding --
2 maintaining effective controls of
3 diversion. The regulations
4 support that the onus is on the
5 registrant to design and operate a
6 system that can identify that, to
7 identify a suspicious order. And
8 then it gets into the, is it an
9 excessive size, is it a varying
10 pattern, or is it -- I'm sorry,
11 frequency, unusual frequency. So
12 they're not -- you know, it's not
13 an all-encompassing list of
14 things.

15 We've given guidance since
16 then on those things.

17 BY MS. MAINIGI:

18 Q. Did the DEA tell registrants
19 in the 1990s that excessive order
20 reporting systems did not meet their
21 suspicious order reporting requirements?

22 A. I'm not sure if they -- no,
23 I'm not sure that -- I know there was
24 discussions that you need to also

1 identify the suspicious order. So we --
2 we distinctly separated the excessive
3 purchase -- or excessive purchase orders
4 were post and that suspicious orders were
5 before the consummation of the
6 transaction. So we were -- we -- we did
7 articulate that at sites and during
8 investigations that there was the
9 difference between the two.

10 Q. Does the DEA have any record
11 evidence of that sitting here today?

12 A. Oh, I don't know what you
13 have in your stack.

14 Q. Well, you looked at a stack
15 back at the office, right?

16 A. Yes.

17 Q. In your stack did you find
18 the DEA telling registrants in the 1990s,
19 oh, also make sure you're doing this
20 separate suspicious order reporting?

21 A. And I saw letters that said
22 that.

23 Q. You did?

24 A. Yes.

1 MS. MAINIGI: Okay. I'd ask
2 the government to go ahead and
3 produce those letters that said
4 that, that Mr. Prevoznik reviewed
5 apparently in preparation for
6 today.

7 BY MS. MAINIGI:

8 Q. Who are those letters to?

9 A. Registrants.

10 Q. Do you remember any
11 particular ones?

12 A. Not off the top of my head.

13 Q. I see. Now, you noted that
14 from time to time while you were out in
15 the field the registrants would report
16 suspicious orders in your view, right?

17 A. I don't think I said that.

18 Q. Well, you said you would get
19 excessive order reports or excessive
20 purchase reports and you would also get
21 suspicious orders sometimes --

22 A. On occasion -- on occasion.

23 Q. On occasion --

24 A. And most of that -- most of

1 that was chemicals, because we were
2 dealing -- in the 1990s we were dealing
3 with the methamphetamine issue at that
4 time.

5 Q. And how about the early
6 aughts? Let's say through 2004. Were
7 you getting the excessive purchase
8 reports and also on occasion suspicious
9 order reporting?

10 A. I think we got both.

11 Q. And how often were you
12 getting the suspicious order reporting
13 through 2004, let's say approximately?

14 A. Not as often as the
15 excessive purchases.

16 Q. So, how often?

17 A. I mean it could be weekly,
18 it could be monthly.

19 Q. And from all the
20 distributors, or are you saying that
21 maybe once a month or once a week you
22 might have gotten a report of a
23 suspicious order?

24 A. Oh, I don't -- I don't know

1 that I -- I don't know that it was once a
2 week. I mean, it was -- a suspicious
3 order? It -- it was pretty rare that --
4 for -- for controlled substances, right?

5 Q. Correct, correct.

6 A. Yes. Yes. Those were
7 pretty rare.

8 Q. And as a diversion
9 investigator, did you ever say to your
10 supervisors or headquarters, I'm asking
11 you now personally, hey, shouldn't we be
12 getting more suspicious order reporting
13 related to controlled substances?

14 MR. FINKELSTEIN: Objection.
15 Scope.

16 THE WITNESS: I don't know
17 that I articulated that.
18 Especially, especially during that
19 time period, because I was in
20 training. So I wasn't in the
21 field at that time.

22 BY MS. MAINIGI:

23 Q. Well, when you were in the
24 field.

1 So anytime you were in the
2 field or in training, did you ever -- did
3 you ever get -- did you ever say to your
4 supervisors or headquarters, hey,
5 shouldn't we be getting more suspicious
6 order reporting on controlled substances?

7 MR. FINKELSTEIN: Objection.
8 Scope.

9 THE WITNESS: Well, back
10 then, it was much more of a
11 regional local issue that we were
12 dealing with, in terms of
13 diversion. It's with the onset of
14 the internet where it became
15 national. So it really changed
16 the dynamic of diversion when it
17 went to the internet.

18 BY MS. MAINIGI:

19 Q. Are you aware of -- are you
20 aware that the case you're here giving a
21 deposition in relates to the state of
22 Ohio, the jurisdictions are in the state
23 of Ohio?

24 MR. FINKELSTEIN: Objection.

1 Scope.

2 THE WITNESS: I'm aware of
3 that.

4 BY MS. MAINIGI:

5 Q. And do you have knowledge of
6 the amount of suspicious order reporting
7 that was -- the frequency of the
8 suspicious order reporting that was
9 occurring in -- related to jurisdictions
10 in Ohio from let's say 1996 through 2004?

11 MR. FINKELSTEIN: Objection.
12 Scope.

13 THE WITNESS: I'm not aware.
14 BY MS. MAINIGI:

15 Q. But where you were in
16 New Jersey and Philadelphia, it was
17 relatively rare during that time period?

18 MR. FARRELL: Objection.
19 Outside the scope of personal
20 knowledge.

21 THE WITNESS: Am I answering
22 as me or the agency?

23 BY MS. MAINIGI:

24 Q. I'm asking you now, in your

1 personal capacity. We already did the
2 corporate.

3 A. Okay. So, could you please
4 repeat the question?

5 Q. Sure. You were a diversion
6 investigator in early '90s and early
7 aughts in New Jersey and Pennsylvania,
8 right?

9 A. Yes.

10 Q. How often did you see
11 suspicious order reporting?

12 A. Like I said, it was more
13 chemicals.

14 MR. FARRELL: Excuse me. I
15 need to place an objection and
16 clarification.

17 Is the DEA putting up
18 Mr. Prevoznik today in his
19 individual capacity for
20 examination?

21 MR. FINKELSTEIN: No.

22 MS. MAINIGI: The usual
23 protocol, Paul, to answer the
24 question that you're about to

1 formulate, I think, is that the
2 practice in a deposition of a
3 30(b)(6) witness is if the witness
4 can't answer a question
5 necessarily in a corporate
6 capacity or is asked a question in
7 a personal capacity, that you
8 can't -- it's not proper to
9 instruct the witness not to
10 answer.

11 It may be that it's
12 ultimately not admissible, but --
13 but you can't instruct the witness
14 not to answer in my understanding.

15 MR. FINKELSTEIN: And I'll
16 note for the record that no one's
17 instructed the witness not to
18 answer.

19 But I will admonish the
20 plaintiffs to the extent that they
21 are tempted to do so, to let me
22 make such instructions.

23 MR. FARRELL: I'm trying to
24 figure out what I just got

1 admonished for.

2 MR. FINKELSTEIN: You
3 didn't. You didn't instruct him
4 not to answer. I'm just noting
5 that no one instructed him not to
6 answer yet.

7 MR. FARRELL: I guess what
8 I'm trying to prepare myself for
9 is that when it's my turn to ask
10 questions, that I get to ask him
11 questions --

12 MS. MAINIGI: Can we not
13 take up time right now? Off the
14 record you can have that
15 discussion.

16 MR. FARRELL: I just got
17 admonished again.

18 BY MS. MAINIGI:

19 Q. The -- the rare cases of
20 suspicious order reporting,
21 Mr. Prevoznik, that -- that you
22 referenced, in what form might that
23 reporting come?

24 Would it be a fax, would it

1 be a phone call? What forms do you
2 recall?

3 MR. FINKELSTEIN: Objection.
4 Vague as to time.

5 THE WITNESS: I don't -- I
6 don't remember off the top of my
7 head what it looked like. It was
8 usually -- back then it was paper.

9 BY MS. MAINIGI:

10 Q. Is it fair to say that from
11 time to time you might get a report of a
12 suspicious order via a telephone call
13 from a distributor?

14 MR. FINKELSTEIN: Objection.
15 Vague as to time.

16 THE WITNESS: I'm not aware.
17 BY MS. MAINIGI:

18 Q. When you say --

19 A. It could be chemical, we
20 might have somebody call.

21 Q. But you don't think a
22 suspicious order for a controlled would
23 come in via a telephone call?

24 MR. FINKELSTEIN: Objection.

1 Vague as to time.

2 THE WITNESS: It could. But

3 I'm not aware of it.

4 BY MS. MAINIGI:

5 Q. Meaning you just never
6 received one?

7 A. Me personally, no, I never
8 received one.

9 Q. Why would it be more
10 frequent, a telephone call for chemicals?

11 A. Well, back then, that was --
12 when I was in the field in Philadelphia,
13 that was the big issue was
14 methamphetamine. So some of the
15 chemicals that were being used illicitly,
16 we would get calls from various companies
17 and informants.

18 Q. Now, you referenced internet
19 pharmacies becoming a big problem at some
20 point in time, correct?

21 MR. FINKELSTEIN: Objection
22 to the characterization.

23 THE WITNESS: Correct.

24 BY MS. MAINIGI:

1 Q. And did the advent of
2 internet pharmacies bring about a greater
3 problem with controlled substances?

4 MR. FINKELSTEIN: Objection.
5 Vague.

6 THE WITNESS: I believe what
7 I said, it went from a
8 local/regional issue to a national
9 issue.

10 BY MS. MAINIGI:

11 Q. The internet pharmacy
12 problem caused the DEA, or prompted the
13 DEA to launch the internet distributor
14 initiative in late 2005, correct?

15 A. Yes.

16 Q. And the purpose of the
17 initiative was to educate DEA registrants
18 regarding their obligations and possible
19 role in supplying internet pharmacies; is
20 that right?

21 A. Yes.

22 Q. And the internet distributor
23 initiative entailed meeting with
24 individual registrants?

1 A. Correct. Again, some of
2 them had more than one registration, so
3 we were doing it more corporate.

4 Q. And as I understand it,
5 there was a PowerPoint presentation that
6 was reviewed with the registrant as a
7 general matter during these meetings?

8 A. Correct.

9 Q. And was that -- we saw in
10 Mr. Wright's deposition the PowerPoint
11 presentation that was used in, let's say
12 the '05, '06 time period. Are you aware
13 of a later PowerPoint that's used in '08,
14 '09, '10?

15 A. Yeah. Yeah. It changed.

16 Q. And you've reviewed those
17 for the purposes of your deposition?

18 A. Mm-hmm.

19 MR. FINKELSTEIN: Answer
20 audibly.

21 THE WITNESS: Yes. Sorry.

22 BY MS. MAINIGI:

23 Q. And what's the difference
24 that you see, because I'm not aware of

1 seeing the later ones?

2 MS. MAINIGI: So, Counsel,
3 I'd ask that you produce those, if
4 you haven't.

5 BY MS. MAINIGI:

6 Q. What's the evolution you see
7 from the earlier drafts to the later
8 drafts?

9 MR. FINKELSTEIN: Hang on.
10 I'll represent that one's in the
11 binder.

12 You can answer.

13 MS. MAINIGI: So you're
14 saying that you just produced it
15 today?

16 MR. FINKELSTEIN: No. I'm
17 saying it's been produced
18 previously.

19 THE WITNESS: Yeah, can I
20 look at my binder?

21 BY MS. MAINIGI:

22 Q. Well, my question really
23 relates to what you're recalling as far
24 as the evolution --

1 A. That's fine.

2 Q. -- from the earlier
3 briefings to the later briefings.

4 A. Right. So the earlier ones
5 focused more on the internet. But there
6 were questions that could also be
7 applicable to what happened later, such
8 as the percentage between noncontrolled
9 and controlled, those types -- those
10 types of things.

11 In the later stages it was
12 more the red flags that we received from
13 the pain clinics, talking about cocktails
14 and various different things. Different
15 drugs. Again, it was their data that we
16 used to show it.

17 Q. So the earlier time period
18 would be '05, '06 and '07?

19 A. I mean, still going in '08,
20 because the Ryan Haight Act didn't come
21 in until 2008.

22 Q. And then the change in
23 emphasis to the red flags from the pain
24 clinics was essentially '09 forward?

1 A. I think it was still
2 evolving probably then, because that -- a
3 lot -- we were doing a lot of stuff down
4 in Florida at that time. So it was
5 probably still in that transition phase
6 of going into more of the red flags.

7 Q. And then did -- did it
8 evolve again from the red flags related
9 to the pain clinics into something else?

10 MR. FINKELSTEIN: Objection.
11 Vague.

12 THE WITNESS: Yeah, I mean
13 it's still -- I mean, the crux of
14 it is still what are the
15 requirements, what are your
16 recordkeeping requirements, what
17 is your responsibilities. It's
18 still all that. So the shift is
19 more of maybe the drugs may have
20 changed a little bit. Trends --
21 trends are going different ways.

22 BY MS. MAINIGI:

23 Q. In terms of the trends and
24 the emphasis, you said you're still doing

1 distributor initiative meetings through
2 today, right?

3 A. I don't know if we have any
4 today. But we've done some recently,
5 yes.

6 Q. Okay. The more recent ones,
7 where is the focus and where is the
8 trends?

9 A. Well, I think what we've
10 been showing, and as it's been reported,
11 we're seeing a decline in the number of
12 opioid prescriptions. We've seen
13 increase in amphetamines and
14 methylphenidate. We're seeing -- the one
15 opioid we still see an increase in is
16 Suboxone, buprenorphine, for drug
17 treatment. We're seeing a little bit of
18 shift of the drugs.

19 Q. So the trends and the
20 problem areas are unfortunately always
21 changing and shifting. Is that fair?

22 A. Well, there tends to be a
23 shift, yeah.

24 Q. And the DEA does its best to

1 try to identify the changes and the
2 shifts in the trends, correct?

3 A. Well, I mean, the data --
4 the data shows that, so it's not DEA
5 doing it. You know, there's been a lot
6 of hard work by a lot -- a lot of
7 different people, including the industry.
8 So...

9 Q. The data from the industry
10 helps everyone identify the shifts in the
11 trends, correct?

12 A. Yeah.

13 Q. Including the DEA?

14 A. Yeah. Yes.

15 Q. And because of the shifts in
16 the trends and the fact that there is a
17 constant change, is that one of the
18 reasons why the DEA takes the position
19 that registrants must design their own
20 system for suspicious order monitoring
21 and reporting?

22 MR. FINKELSTEIN: Objection.

23 Vague.

24 THE WITNESS: I don't think

1 that's our -- I mean, it's what
2 Congress passed and enacted, so
3 the onus -- they put the onus on
4 the registrant.

5 BY MS. MAINIGI:

6 Q. With respect to the
7 expectations of the DEA, is it fair to
8 say that the DEA expects registrants to
9 regularly update their suspicious order
10 monitoring systems to be responsive to
11 the change in trends?

12 A. Yeah. You would hope they
13 would.

14 Q. Coming back to the
15 Rannazzisi letter from December of '07,
16 if you would, please. I'm on the third
17 paragraph. Let me know when you're
18 ready.

19 A. Okay. The one that starts,
20 "The regulation"?

21 Q. Yes. So as we discussed
22 earlier, Mr. Prevoznik, this letter says,
23 "The regulation also requires that the
24 registrant inform the local DEA division

1 of suspicious orders when discovered by
2 the registrant," correct?

3 A. Correct.

4 Q. And "when discovered" is a
5 proxy for prior to shipping; is that
6 right?

7 MR. FINKELSTEIN: Objection.
8 Vague.

9 THE WITNESS: Correct.

10 BY MS. MAINIGI:

11 Q. So, this letter is advising
12 registrants that they should stop
13 shipment of orders that they deem
14 suspicious, correct?

15 MR. FINKELSTEIN: Objection.
16 Form.

17 THE WITNESS: Well, it's
18 reiterating what the regulations
19 are. It's not advising. It's
20 reiterating the responsibilities
21 of -- of what they are supposed to
22 do.

23 BY MS. MAINIGI:

24 Q. Does --

1 A. So yes, they're -- we're
2 highlighting that they should be looking
3 at that to maintain effective controls
4 guarding against diversion.

5 Q. Did the Controlled
6 Substances Act contain any language that
7 states whether or not a distributor could
8 ship a suspicious order?

9 A. It doesn't say specifically
10 that. It does say that it needs to be --
11 it has to maintain -- maintain effective
12 control against diversion.

13 Q. Is it fair to say -- now at
14 this point in time, 2007, remind me where
15 you were. You were still in the field?

16 A. This is probably the hardest
17 question.

18 Q. I have your CV here so I can
19 tell you.

20 A. I was in Atlantic City.

21 Q. Yes, you were.

22 MR. FINKELSTEIN: Could the
23 people on the phone put their
24 phones on mute if they are not

1 going to talk?

2 BY MS. MAINIGI:

3 Q. Is it fair to say that in
4 this time period, let's say, 2007-2008,
5 there was confusion among registrants
6 about the do-not-ship policy?

7 MR. FINKELSTEIN: Objection.
8 Calls for speculation.

9 THE WITNESS: I -- I don't
10 believe so.

11 BY MS. MAINIGI:

12 Q. You don't think so?

13 A. No.

14 Q. You don't recall in the
15 field getting questions about what the
16 do-not-ship policy meant?

17 MR. FINKELSTEIN: Objection.
18 Scope.

19 THE WITNESS: The -- what --
20 what was, was the registrant --
21 was the registrant had to make the
22 decision whether to ship or not.

23 So that goes back to the
24 statute that says, do you have --

1 do you maintain effective control
2 against diversion. So that's
3 where that goes from. So the --
4 the distributor has to make that
5 decision whether to ship or not
6 ship.

7 And we have said in past
8 stuff that that is -- that you
9 need to identify those and not --
10 and it's -- just because you
11 report it, doesn't mean you're
12 exonerated from it. You still
13 have to maintain effective control
14 over it.

15 So, you know, that's --
16 that's a business decision for
17 them to ship or not ship. But it
18 still falls under the statute of
19 what's the effective means that
20 you're guarding against diversion.

21 BY MS. MAINIGI:

22 Q. I have forgotten what
23 question I asked you.

24 MR. FINKELSTEIN: Is that a

1 question?

2 MS. MAINIGI: Let me -- let
3 me re-ask the question.

4 BY MS. MAINIGI:

5 Q. Do you recall when you were
6 in the field, in this time period,
7 '07-'08, getting questions either from
8 other diversion investigators or from
9 registrants about what the do-not-ship
10 policy meant?

11 MR. FINKELSTEIN: Objection.
12 Scope.

13 THE WITNESS: Is this -- can
14 I ask, is this me personally --

15 BY MS. MAINIGI:

16 Q. Yes.

17 A. -- or is this -- I am not
18 aware of that.

19 Q. Are you generally aware from
20 all the people that you talked to at the
21 DEA, are you generally aware as the DEA,
22 that in the '07-'08 time period, there
23 was confusion in the industry as to the
24 meaning of the do-not-ship policy?

1 MR. FINKELSTEIN: Object to
2 the characterization.

3 THE WITNESS: For the people
4 I talked to? I'm just trying to
5 remember what we -- what we talked
6 about.

7 It was -- from my
8 recollection of talking to the
9 folks was that again it was a
10 business decision on whether to
11 ship or not ship. That we, DEA
12 were not going to direct a
13 registrant don't ship or not ship
14 at that time.

15 BY MS. MAINIGI:

16 Q. In 2008?

17 A. So -- I'm sorry, 2 -- no,
18 that was prior to that. Because in -- in
19 '7 that's when it came out that --

20 Q. So in '7 it was clear that
21 you were now directing registrants do not
22 ship?

23 A. Right. Because of --
24 because of the internet.

1 Q. And prior to 2 --

2 December 2007 it was a business decision
3 by each registrant recognizing what their
4 own obligations were?

5 A. Correct.

6 Q. Okay. And so how could
7 there not have been confusion about that
8 shift, the DEA went from it's up to you,
9 to we're telling you not to ship?

10 Didn't that create confusion
11 for some period of time?

12 MR. FINKELSTEIN: Objection.
13 Scope. Calls for speculation.

14 THE WITNESS: Well, I don't
15 know if there was confusion or
16 not. Because the -- quite a few
17 registrants continued to do what
18 they continued to do, which was
19 continued to sell, to ignore
20 suspicious orders and they would
21 continue to sell huge volumes down
22 the line through retail --

23 BY MS. MAINIGI:

24 Q. And ship to suspicious

1 orders?

2 A. Right. So they weren't
3 following our obligation to maintain
4 effective controls. That's why we --
5 that's why we had settlements with them,
6 civil settlements. And then we started
7 meeting with them and getting into MOAs,
8 about you need to report them to the
9 headquarters now, because you're not
10 following what you're supposed to be
11 doing.

12 Q. And in the meeting with
13 distributors, you've not heard anyone
14 report that there was confusion about the
15 changes to the policy?

16 A. No, not -- not me
17 personally.

18 Q. Well, in the interviews you
19 did for this -- this deposition.

20 A. I am not aware.

21 Q. Okay. Now, given the shift
22 in focus with respect to internet
23 pharmacies and given the shift with
24 respect to the do-not-ship policy, the

1 DEA understood that its new suspicious
2 order policy would require registrants to
3 either -- to either enhance or supplement
4 their suspicious order monitoring
5 systems, right?

6 MR. FINKELSTEIN: Object to
7 the characterization.

8 THE WITNESS: Well, I would
9 say from the distributor
10 initiatives, when we sat down with
11 them in '05, '06, '07, that they
12 were already told they've got to
13 change something because you are
14 not doing what you are supposed to
15 do. And the hope was that they
16 would do it. But they didn't do
17 it.

18 Again, it goes back to, you
19 can -- you can have the best
20 policy in the world, that's going
21 to, you know, identify every bad
22 suspicious order out there. And
23 then you can choose to ignore it.
24 So...

1 BY MS. MAINIGI:

2 Q. So, the -- I'm sorry.

3 A. Go ahead.

4 Q. I didn't mean to interrupt
5 you. Are you --

6 A. Yeah.

7 Q. Okay. So in '05, '06 and
8 '07, as I understand it from Mr. Wright's
9 testimony, he and Mr. Mapes primarily
10 handled the distributor initiative
11 briefings, correct?

12 A. Correct.

13 Q. And you have talked to
14 neither Mr. Wright nor Mr. Mapes,
15 correct?

16 A. Correct.

17 Q. So you don't know sitting
18 here today what Mr. Mapes or Mr. Wright
19 said or heard in those distributor
20 initiative briefings, correct?

21 MR. FINKELSTEIN: Objection.
22 Argumentive.

23 THE WITNESS: No.

24 BY MS. MAINIGI:

1 Q. The people you have talked
2 to in preparation for this deposition,
3 are the people that went to the
4 distributor initiative briefings
5 beginning in '08; is that right?

6 A. Yes. But let me clarify.
7 I -- I had the PowerPoints that Mr. Mapes
8 and Kyle gave. We have the written
9 summaries that they did after they met
10 with them. So I have a good idea of what
11 was said at those meetings and what was
12 covered.

13 Q. And the primary piece of
14 information that you have is the
15 PowerPoint?

16 MR. FINKELSTEIN: Objection.
17 Misstates the witness's testimony.

18 THE WITNESS: And the
19 report.

20 MR. FINKELSTEIN: I'm going
21 to ask that we take our lunch
22 break soon.

23 MS. MAINIGI: Okay. I
24 thought you wanted to keep going.

1 So I was trying to honor that.

2 MR. FINKELSTEIN: What I
3 said was five-minutes breaks.

4 MS. MAINIGI: But let me get
5 to a good breaking point.

6 MR. FINKELSTEIN: How much
7 more?

8 MS. MAINIGI: I don't know,
9 but give me a second to evaluate
10 where a good breaking point would
11 be. But I understand your
12 request, and I will do my best to
13 honor it.

14 BY MS. MAINIGI:

15 Q. After this Rannazzisi
16 letter, the December 2007 Rannazzisi
17 letter, did DEA provide any guidance to
18 registrants as to how to design or
19 implement their suspicious order
20 monitoring systems?

21 A. Well, yeah, with the MOAs
22 that we -- and settlements that we got
23 with them.

24 Q. And in the MOA meetings, you

1 provided guidance as to what your
2 expectations were as to the suspicious
3 order monitoring systems going forward,
4 correct?

5 A. That's where we -- yes.

6 Q. What about the distributors
7 that didn't have MOAs? How did they get
8 guidance from the DEA as to how to design
9 their -- or implement their suspicious
10 order monitoring systems in 2008 forward?

11 A. So it would be through the
12 distributor, if we did an initiative with
13 them. It could be through the
14 pharmaceutical conferences. Again, I'm
15 not sure when we -- when we did them.
16 But it would be through that. It would
17 be through their scheduled investigations
18 when we're out there.

19 Q. So essentially there was no
20 industrywide guidance that was provided
21 in 2008 or forward as to how to design or
22 implement suspicious order monitoring
23 systems, true?

24 MR. FINKELSTEIN: Object to

1 the characterization.

2 THE WITNESS: Nationwide,
3 correct.

4 BY MS. MAINIGI:

5 Q. Instead, one-off guidance
6 was perhaps provided in the context of
7 individual distributor meetings, correct?

8 A. Yes. Along with the MOAs
9 and the settlements that were done.

10 Q. And is there documentation
11 of what was said at the individual
12 distributor meetings?

13 A. It would be the PowerPoints
14 and the report -- after report.

15 Q. And this is an internal DEA
16 report?

17 A. Yes.

18 Q. And have you reviewed those
19 internal DEA reports for the purpose of
20 preparing for your testimony today?

21 A. Some of them.

22 Q. Now, does the DEA agree that
23 there's more than one way to design and
24 operate a system that can identify and

1 report suspicious orders?

2 A. Yes.

3 Q. And there's no single
4 feature that makes a suspicious order
5 monitoring system compliant, correct?

6 A. Correct.

7 Q. And the DEA leaves it up to
8 the registrant to design a system that
9 works with its own business model and
10 customer base, correct?

11 A. Correct.

12 Q. Does it matter to the DEA
13 whether a registrant reviews orders
14 manually or uses an automated system?

15 A. No, it doesn't matter.

16 Q. Other than requiring that
17 the report, suspicious order report
18 clearly indicate that the order is
19 suspicious, does DEA require suspicious
20 order reports to follow a particular
21 format?

22 A. That's correct.

23 Q. Let me ask the question
24 again. The DEA does not require

1 suspicious order reports to follow a
2 particular format, correct?

3 A. Well, I mean, they have to
4 follow what the regs say about unusual
5 size, unusual patterns, or frequency. I
6 mean, that's in there. We also ask that
7 the red flags and, you know, looking at
8 newspapers articles to see, you know,
9 what the overdoses are. You know, are
10 they looking at more than just the data,
11 because the data is only as good as --
12 you know, you can set the threshold too
13 high, you can set it too -- it's never
14 going to pick up something, or you're not
15 going to see patterns, because it's a new
16 customer that gets onboarded, and they're
17 already high, and you don't question it
18 or you don't look at it, you don't see
19 the population size, you don't see what's
20 their percentage of control versus not
21 control. I mean, there's a lot of
22 different factors that go in it. So
23 however they design it, they need to get
24 the big picture so that they truly know

1 what is their customer doing.

2 Q. Is there --

3 MR. FINKELSTEIN: Hang on.

4 Five minutes ago, I asked for a
5 break. We've been on the record
6 for more than an hour and a half.
7 Can you tell us when you are going
8 to be done?

9 MS. MAINIGI: Just a couple
10 more minutes.

11 BY MS. MAINIGI:

12 Q. Is the review -- is it fair
13 to say then that the identification of
14 suspicious orders can be a subjective
15 process?

16 MR. FINKELSTEIN: Objection.
17 Vague.

18 THE WITNESS: What do you
19 mean by "subjective"?

20 BY MS. MAINIGI:

21 Q. Well, do you understand the
22 meaning of the word "subjective"?

23 A. I'm asking you in terms of
24 this, what do you mean by subjective?

1 Q. Well, what I mean is that
2 you and I looking at the same data,
3 sometimes, not always, may come to
4 different conclusions, as to whether an
5 order is suspicious. Is that possible?

6 A. That is --

7 MR. FINKELSTEIN: Hang on.

8 Objection. Calls for speculation.

9 BY MS. MAINIGI:

10 Q. I didn't hear -- you said
11 that is --

12 A. That is possible.

13 Q. And so, therefore, the
14 identification of suspicious orders is a
15 somewhat subjective process?

16 MR. FINKELSTEIN: Objection.
17 Vague.

18 THE WITNESS: I mean, when
19 it comes down to a suspicious
20 orders, what is triggering may --
21 it's the whole point of the
22 suspicious order is to identify --
23 hold on one second. Okay.

24 A suspicious order is an

1 order in which the recipient of
2 the order detects through their
3 suspicious order monitoring
4 system, a reason or reasons that
5 may indicate that that order may
6 be -- that order may be diverted
7 outside the legitimate scientific,
8 medical, and industry channels.
9 That's what it is.

10 So the subjectivity would be
11 not just us looking at it. I
12 mean, we would look at it. They
13 would look at it. And that's why
14 many have gotten in trouble,
15 because they didn't look at it and
16 changed stuff. So, you know, when
17 we get -- if we go to court or
18 whatever, it's going to be up to
19 the jury and the judge to decide.

20 BY MS. MAINIGI:

21 Q. Because it's subjective,
22 right?

23 MR. FINKELSTEIN: Objection.
24 Vague.

1 THE WITNESS: Yeah, it can
2 be subjective.

3 MS. MAINIGI: Let's take a
4 break.

5 THE VIDEOGRAPHER: All
6 parties agree to go off the
7 record?

8 MR. FINKELSTEIN: Yes.
9 Thank you.

10 THE VIDEOGRAPHER: Thank
11 you. 12:24, we are off the video
12 record.

13 - - -

14 (Lunch break.)

15 - - -

16 A F T E R N O O N S E S S I O N

17 - - -

18 THE VIDEOGRAPHER: 1:32, we
19 are on the video record.

20 BY MS. MAINIGI:

21 Q. Good afternoon. Let me hand
22 you Exhibit 6 to take a look at.

23 (Document marked for
24 identification as Exhibit

1 DEA-Prevoznik-6.)

2 BY MS. MAINIGI:

3 Q. Exhibit 6 is what -- what --
4 let me ask you first as you're reviewing
5 this document.

6 Did -- did you review this
7 back and forth during the course of your
8 prep for this deposition?

9 A. No, I did not.

10 Q. Okay. So let's start with
11 the attachment, the first letter that
12 came -- excuse me -- from the NCPA.

13 Are you familiar with that
14 group, the NCPA?

15 A. No.

16 Q. The National Community
17 Pharmacists Association.

18 The National Community
19 Pharmacy Association sent a letter to
20 Mr. Rannazzisi dated March 7, 2008. Do
21 you see that?

22 A. Yes.

23 Q. And in their letter they
24 reference Mr. Rannazzisi's December 27,

1 2007, letter to manufacturers and
2 distributor registrants. Do you see
3 that, in the fourth paragraph?

4 A. Could I just ask, since I
5 haven't seen it, could I just review it?

6 Q. Sure, of course.

7 A. I apologize.

8 Q. Please go ahead.

9 A. Okay.

10 Q. So a trade association of
11 community pharmacists sent Mr. Rannazzisi
12 a letter in March of 2008, correct?

13 A. Correct.

14 Q. And as you saw from the
15 letter, the registrants, the -- the group
16 of community pharmacists voiced concerns,
17 about the potential implications of the
18 distributors' anti-diversion efforts on
19 patient care.

20 Did you get that from the
21 letter?

22 A. Yes.

23 Q. And if you take a look at
24 the third paragraph, they note in

1 italics, "We write to express our concern
2 that recent efforts by DEA aimed at
3 pharmaceutical wholesalers and
4 distributors to combat the illicit
5 distribution of controlled substances
6 have had unintended consequences and are
7 harming patient care."

8 Do you see that?

9 A. Yes.

10 Q. And then in the next
11 paragraph the writer of the letter ties
12 this recent action to Mr. Rannazzisi's
13 December 2007 letter that we just
14 reviewed -- reviewed a little while ago.
15 Do you see that?

16 A. Yes.

17 Q. And the first sentence of
18 that paragraph states, "Perhaps the key
19 factor in wholesalers acting overbroadly
20 is your December 27, 2007, letter to
21 manufacturer and distributor registrants
22 of controlled substances."

23 Do you see that?

24 A. Yes.

1 Q. Is it -- was the DEA aware
2 that distributors took the type of
3 actions that were described in this
4 letter in the aftermath of
5 Mr. Rannazzisi's December 27, 2007,
6 letter?

7 MR. FINKELSTEIN: Objection.
8 Vague.

9 THE WITNESS: I'm not sure I
10 understand your question.

11 BY MS. MAINIGI:

12 Q. Well, was the DEA aware --
13 let me ask it more generically.

14 A. Sure.

15 Q. Was the DEA aware that in
16 the aftermath of -- of Mr. Rannazzisi's
17 December 27, 2007, letter, that the
18 distributors were doing their best to
19 comply with what they perceived as
20 stepped up -- stepped up interpretations
21 of the regulations?

22 MS. SINGER: Objection.
23 Lack of foundation.

24 MR. FINKELSTEIN: Objection

1 to the characterization.

2 You can answer.

3 THE WITNESS: One more time.

4 BY MS. MAINIGI:

5 Q. Did --

6 A. I apologize. I just want to
7 make sure I got it.

8 Q. No, no, no, no. Let me try
9 it another way.

10 Did -- did the -- so we have
11 the -- the Rannazzisi December 27, 2007,
12 letter, correct?

13 And I think that in the file
14 there are lots of letters and issues in
15 the aftermath of that December 27, 2007,
16 letter. And this letter is just one of
17 them, in March of 2008.

18 Did DEA understand that in
19 the aftermath of Mr. Rannazzisi's
20 December 27, 2007, letter, that
21 distributors took actions that resulted
22 in a number of complaints by pharmacies
23 that distributors were acting
24 precipitously?

1 MR. FINKELSTEIN: Objection.

2 Vague.

3 THE WITNESS: We -- we heard
4 complaints.

5 BY MS. MAINIGI:

6 Q. Complaints from whom?

7 A. From -- it could be
8 pharmacies. It could be -- it could be
9 patients saying I can't get my meds.

10 Q. And so there were complaints
11 from pharmacies, kind of the variety we
12 see in Exhibit 6, basically saying
13 distributors are taking actions that are
14 unfair to the pharmacies as a result of
15 Mr. Rannazzisi's letter, true?

16 MR. FINKELSTEIN: Objection.
17 Mischaracterizes.

18 THE WITNESS: I'm not sure
19 that it's just the letter, because
20 this was also the time that we
21 started getting into settlement
22 agreements with the industry as
23 well. So it wasn't just the
24 letter. It was...

1 BY MS. MAINIGI:

2 Q. But there was -- I'm sorry.

3 A. No. Go ahead.

4 Q. But there was -- and so
5 there were complaints from pharmacies to
6 the DEA, correct?

7 A. Correct.

8 Q. And there were complaints
9 from patients to the DEA also, correct?

10 A. Yeah.

11 Q. And this is -- these are
12 complaints from patients who are worried
13 that they are not able to get their meds
14 because distributors are restricting
15 their distribution of meds in part as a
16 result of the various actions with DEA,
17 correct?

18 MS. SINGER: Objection.

19 Lacks foundation.

20 THE WITNESS: I'm not -- I'm
21 not sure that that's completely
22 correct. The -- the actions that
23 we were taking were against
24 internet pharmacies, so

1 pharmacists that the public would
2 walk into. That was not -- we
3 were targeting -- we were dealing
4 with this certain group of
5 registrants that are out of line,
6 that are not maintaining effective
7 controls. And that's what we
8 targeted. So we were -- we were
9 targeting the internet pharmacies
10 at this time.

11 So if --

12 BY MS. MAINIGI:

13 Q. At the time of Exhibit 6?

14 A. Well, no, I mean, this is --
15 this was the culmination of litigations
16 and investigations and, you know. Again
17 like I said, we were getting into
18 settlements with some of the distributors
19 on, you know, you didn't do what you --
20 you said you were going to change, you
21 didn't change. Now we're at the table
22 trying to settle this, and -- and, you
23 know, hopefully protect the public
24 health. That -- that was the goal.

1 I mean part of -- the other
2 part of our mission besides preventing
3 and detecting and investigating the
4 diversion is we also had the
5 responsibility to ensure that there's
6 enough for -- of an adequate supply. So,
7 a twofold mission. So...

8 Q. So was the perception of
9 some in the market that the distributors
10 had overreacted to what DEA was saying?

11 MR. FINKELSTEIN: Objection.
12 Scope, calls for speculation.

13 THE WITNESS: I -- I don't
14 know what the wholesalers were
15 thinking. I -- if -- I mean, I
16 know from my own experience with
17 the -- with the pharmacy diversion
18 awareness conferences where we had
19 pharmacists coming up and saying
20 hey, they are putting thresholds
21 on, they are cutting us off, this
22 is affecting patient care. And
23 they said well, DEA sets the
24 threshold. And we said, no,

1 that's not true, we did not set
2 the thresholds. The industry sets
3 the thresholds.

4 That was an eye-opener for
5 them, because they were being
6 told -- somebody was telling them
7 the DEA set thresholds. We don't
8 set thresholds on that -- on that
9 part, with -- in regards to that.

10 So, pushing back, you know,
11 and then you get -- then we -- we
12 take action against pharmacists,
13 you have a similar situation with
14 a pharmacist saying oh, the DEA
15 said we're not allowed to fill
16 these prescriptions. DEA does
17 not -- does not regulate the
18 practice of medicine. And,
19 those -- you know, that's the
20 pharmacist's decision whether to
21 fill the prescription or not.

22 BY MS. MAINIGI:

23 Q. But it appeared to you that
24 there was an uptick in complaints from

1 pharmacists, pharmacies and patients in
2 the aftermath of the December 2007
3 Rannazzisi letter, correct?

4 A. I think --

5 MR. FINKELSTEIN: Objection.
6 Mischaracterizes.

7 THE WITNESS: I think it's
8 both. It's both the letter and
9 the actions that we had taken
10 against them. So I can't say in
11 particular the letter triggered
12 all this, because I think the
13 actions also triggered stuff too.

14 BY MS. MAINIGI:

15 Q. And so the collective
16 actions of DEA, including the Rannazzisi
17 letter, including the settlements and so
18 forth in 2007, you noticed an increase in
19 complaints from pharmacists from seasoned
20 patients in 2008, for example?

21 A. Yes.

22 Q. It was not DEA's intention
23 to interfere with patients' ability to
24 fill legitimate prescriptions for

1 controlled substances, correct?

2 A. Correct.

3 Q. So did DEA provide any
4 additional guidance to distributors to
5 prevent -- to prevent the type of
6 incidents that were complained of from
7 happening?

8 MR. FINKELSTEIN: Objection.
9 Vague.

10 THE WITNESS: I'm not sure
11 what you're asking.

12 BY MS. MAINIGI:

13 Q. Well, so, let's go ahead and
14 take a look at this letter again.

15 The writer of this letter,
16 Mr. Roberts from NCPA, asked the DEA to
17 hold the meeting with wholesalers,
18 consumer groups and community pharmacies
19 so that all parties could clearly
20 understand DEA's expectations and attempt
21 to comply with them, right?

22 A. Just to make sure, on 5917?

23 Q. Yes.

24 A. And specifically the second

1 paragraph?

2 Q. Correct.

3 A. "We did request"?

4 Q. Yes.

5 A. Yes.

6 Q. Okay. The request by the
7 community pharmacists as Mr. Roberts
8 characterizes it, at least, was that the
9 DEA refused to meet with this group,
10 correct?

11 A. Correct.

12 Q. Now, you said that you were
13 not aware of this particular issue as
14 part of your review process, right?

15 A. No. I think you asked me if
16 I had reviewed this letter in particular.
17 I said no.

18 Q. Okay. But was it generally
19 your understanding that in this time
20 period, meaning 2008, that the DEA at
21 that point in time, was declining to meet
22 with registrants or others, to discuss
23 DEA's suspicious order reporting
24 expectations?

1 A. Well, first, NCPA is not a
2 registrant. We were still doing
3 distributor initiatives at that time. So
4 we were still meeting with the industry
5 at that time.

6 Q. The pharmacies may be
7 registrants, right?

8 A. The pharmacies are
9 registrants, yes.

10 Q. So it was a group of
11 pharmacies that wanted to meet with the
12 DEA, wholesalers, and others, to
13 determine what was actually being
14 required by the DEA, and the DEA said no,
15 apparently, according to this letter,
16 correct?

17 A. Correct.

18 MR. FINKELSTEIN: Object to
19 the characterization.

20 BY MS. MAINIGI:

21 Q. And do you have an
22 understanding of why?

23 A. I believe that it was
24 because we were still in the litigation

1 and investigating the pharmacies and
2 wholesalers at that time, that we were
3 either in litigation or still
4 investigating outliers that were still
5 doing those kind of businesses.

6 Q. Now, that's what -- this
7 morning that's what you told me was the
8 reason why you couldn't provide further
9 guidance in the 2010 to 2013 time period,
10 right?

11 MR. FINKELSTEIN: Object to
12 the characterization of the
13 witness's testimony this morning.

14 THE WITNESS: You asked me
15 about this specific meeting, so
16 I'm answering what my
17 understanding --

18 BY MS. MAINIGI:

19 Q. Understood.

20 A. -- what I --

21 MR. FINKELSTEIN: Hang on,
22 let him finish.

23 BY MS. MAINIGI:

24 Q. Sorry. This morning you

1 told me that for the 2010-2013 time
2 period, because of litigation and other
3 things, there were not necessarily
4 briefings or distributor conferences held
5 in that time period correct?

6 A. There were -- we had stopped
7 with the distributor initiative and we
8 had stopped with the conferences with the
9 wholesalers, yes.

10 Q. In 2010 to 2013?

11 A. Right.

12 Q. And you told me the main
13 reason was because of litigation and
14 investigations, right?

15 A. Correct.

16 Q. And is it your position that
17 also in the 2008 to 2010 time period, for
18 the same reason, litigation and
19 investigations, DEA was also unwilling to
20 meet with various constituent groups?

21 MR. FINKELSTEIN: Objection.
22 Vague.

23 THE WITNESS: As I said,
24 this is my -- my belief is that

1 this particular meeting was
2 because -- wasn't held because
3 they are not registrants. We were
4 looking at -- we were doing
5 investigations and litigation
6 against somebody, some pharmacies.
7 Not all of them are independent,
8 some of them are chain. So I
9 think that's probably why this
10 meeting wasn't held.

11 I think that's the question
12 you asked was why we didn't hold
13 this meeting. So I'm trying to
14 answer that question.

15 BY MS. MAINIGI:

16 Q. I thought you said earlier
17 maybe it was because of litigation and
18 investigations this meeting wasn't held?

19 A. I thought that's what I -- I
20 thought I just explained that.

21 Q. Okay. If you look at the
22 cover e-mail response -- well, actually,
23 I apologize. Let's look at the letter
24 from Mr. Rannazzisi. And this letter, I

1 take it, reflects DEA's policy position
2 as of May 2008, correct?

3 A. Correct.

4 Q. And that includes the
5 concept that, if you look at the
6 penultimate paragraph, that DEA, while
7 understanding the concerns that NCPA has
8 raised, is unable to require anything
9 more concerning this matter than what is
10 stated in the Controlled Substance Act
11 and its implementing regulations.

12 Do you see that?

13 A. I'm sorry, where are you at?

14 Q. Second-to-last paragraph.

15 A. Second page?

16 Q. Yes.

17 A. Correct.

18 Q. And so the DEA says, we
19 can't tell you anything more than what
20 the Controlled Substance Act and its
21 implementing regulations say, right?

22 A. Correct.

23 Q. And this communication was
24 sent via e-mail all around the department

1 to senior diversion investigators,
2 diversion program managers and group
3 supervisors.

4 Do you see that?

5 A. Yes.

6 Q. And the e-mail reads in
7 part, "Please be sure to share this
8 information with the diversion
9 investigators in your group."

10 Do you see that?

11 A. Yes.

12 Q. And isn't that because
13 Mr. Rannazzisi's articulation of the
14 DEA's current position was not exactly
15 consistent with the interpretation that
16 DEA had had some years prior?

17 A. I'm not following you.

18 Q. Well, isn't it fair to say
19 that the reason this fairly unremarkable
20 letter from Mr. Rannazzisi was circulated
21 to all of these people was because
22 headquarters wanted to ensure that those
23 in the field understood that this was now
24 the official position of the DEA?

1 A. I don't see any difference
2 between this and the letters that you
3 sent out on the position in '07 to be --
4 to the -- it's repeating exactly what the
5 regulations are.

6 Q. Is it the same as letters
7 that were sent out in '03 or '04 or would
8 those have been different letters?

9 MR. FINKELSTEIN: Objection.
10 Vague.

11 THE WITNESS: I was speaking
12 in terms of the '06 and '07, the
13 reiteration of what the
14 regulations are.

15 BY MS. MAINIGI:

16 Q. Headquarters wanted to
17 ensure in this time period that the field
18 was following the latest guidance from
19 headquarters, as far as diversion
20 control, correct?

21 A. Correct.

22 Q. And that is why, one of the
23 reasons why they sent this e-mail,
24 correct?

1 A. Correct.

2 MR. FARRELL: What was
3 Exhibit 5?

4 MR. FINKELSTEIN: 2007 "Dear
5 Registrant" letter.

6 BY MS. MAINIGI:

7 Q. Let me take you back to that
8 letter for a moment, Mr. Prevoznik, the
9 second paragraph of Mr. Rannazzisi's
10 letter.

11 What does the first sentence
12 of Mr. Rannazzisi's letter dated May 2008
13 say, if you could read it out loud?

14 A. When it starts in addition
15 to?

16 Q. In the last few years.

17 MR. FINKELSTEIN: Now I
18 don't know where you're directing
19 him.

20 BY MS. MAINIGI:

21 Q. The Exhibit 6 that we were
22 just looking at?

23 A. Oh I'm sorry --

24 Q. I'm sorry. That's my fault.

1 A. -- I thought you said you
2 went back to Exhibit 5.

3 Q. Exhibit 6. Mr. Rannazzisi's
4 response, second paragraph, first
5 sentence.

6 Could you read that out
7 loud?

8 A. Sure.

9 "In the last few years there
10 has been a significant" -- "a significant
11 increase in the diversion and abuse of
12 pharmaceutical" -- "pharmaceutical
13 controlled substances."

14 Q. So I think this is
15 consistent with what you were saying
16 earlier this morning, which is, the DEA
17 only noticed an increase in the diversion
18 of prescription opioids in the few years
19 leading up to 2008; is that correct?

20 MR. FARRELL: Objection.
21 Foundation.

22 MR. FINKELSTEIN: Objection.
23 Mischaracterizes the letter.

24 THE WITNESS: I think it's

1 consistent with what I said in
2 regards that this was the
3 beginning of the switch from
4 regional diversion issues of
5 controlled substances to now a
6 national scale of the -- via the
7 internet.

8 BY MS. MAINIGI:

9 Q. Now, Mr. Rannazzisi's
10 response at the bottom of the first page
11 also references a concept called knowing
12 your customer. Do you see that?

13 A. The last sentence?

14 Q. Yes.

15 A. Yes.

16 Q. And specifically the last
17 sentence reads, "DEA encourages
18 manufacturers and wholesalers to know
19 their customers to determine when or if
20 an order for controlled substances meets
21 the designation of suspicious."

22 Do you agree with that
23 sentence?

24 A. Yes.

1 Q. Now, did the Controlled
2 Substances Act in this time period state
3 that the registrants must know their
4 customer to decide whether an order is
5 suspicious or not?

6 A. It does not have that
7 specific language. But the statute still
8 has to maintain effective controls over
9 diversion.

10 And if you also look at
11 1301.71(a), the first sentence there,
12 "All applicants and registrants shall
13 provide effective controls and procedures
14 to guard against theft and diversion of
15 controlled substances."

16 So neither one of those
17 changed from when this got enacted.

18 Q. And is there any DEA
19 regulation that states that in order to
20 determine whether an order is suspicious
21 or not, that a registrant must know their
22 customer to make that decision?

23 A. Could you repeat that?

24 Q. Sure. I'm sorry.

1 Is there any DEA regulation
2 that says in order for a registrant to
3 make a determination as to whether an
4 order is suspicious or not, they must
5 know their customer to decide?

6 A. It doesn't specifically have
7 that language. But again it goes back to
8 the statute of have -- maintaining
9 effective controls to guard against
10 diversion.

11 Q. And --

12 A. So it -- so it's -- it's --
13 it's implicit.

14 Q. Well, it was --

15 A. You have to know -- I
16 mean --

17 Q. Is it -- is it explicit --

18 A. -- if you're going to
19 make --

20 MR. FINKELSTEIN: No, wait,
21 hang on. You're entitled to
22 answer your -- to complete your
23 answer. And when you start to
24 answer, please try to finish your

1 answer.

2 THE WITNESS: Yeah, I

3 apologize.

4 BY MS. MAINIGI:

5 Q. No, no, no, my fault too.

6 A. Where was I?

7 Q. Is the know your customer --
8 I think you've answered my question.

9 The -- the know your
10 customer concept is not explicitly stated
11 in the regulation, correct?

12 A. Correct.

13 Q. And that's true even today,
14 correct?

15 A. Well, I mean it -- it still
16 goes back to maintaining control.

17 I mean, the whole structure
18 of the Controlled Substance Act, the
19 regulations, this is how you do business.
20 If you're going to do it -- be authorized
21 to handle controlled substances, this is
22 the way you're going to do it. So if
23 you're going to be selling to customers,
24 you need to know who your customers are.

1 Q. Today, does the regulation
2 explicitly reference knowing your
3 customer?

4 A. No.

5 Q. Has DEA ever approved or
6 endorsed any specific methodology to be
7 used by manufacturers or distributors to
8 know their customers?

9 MR. FINKELSTEIN: Objection.
10 Vague. Scope.

11 THE WITNESS: Can you please
12 repeat?

13 BY MS. MAINIGI:

14 Q. Sure. Has DEA ever approved
15 or endorsed any specific methodology to
16 be used by manufacturers or distributors
17 to know their customer?

18 MR. FINKELSTEIN: Same
19 objection.

20 THE WITNESS: No.

21 BY MS. MAINIGI:

22 Q. Has DEA ever issued any
23 guidance documents or best practices
24 regarding the methodology that

1 distributors and manufacturers should use
2 to know their customer?

3 A. I mean, the regulations
4 define -- they have to safeguard against
5 diversion.

6 It also identifies what
7 suspicious orders are. So I mean I think
8 that there is guidance in that. We also,
9 with the conferences, and the scheduled
10 investigations that were out there, where
11 we're meeting with the manufacturers and
12 the distributors, that those are
13 opportunities that we also discuss those
14 with them.

15 Q. So we just -- you just
16 referenced the guidance as having best
17 practices in it for knowing your
18 customer?

19 MR. FINKELSTEIN: Objection.
20 Mischaracterizes.

21 THE WITNESS: I don't
22 believe I -- if I -- if that's
23 what you got, I apologize, that's
24 not what I meant. It's not --

1 it's not a guidance thing.

2 It's -- we're talking to
3 them about, you know, they are
4 saying this is their system, we'll
5 look at their system. We'll
6 advise. You know, you might want
7 to think of this. There's --
8 there's varying ways to talk to --
9 to the registrants. And that is
10 what we try to do is talk to them
11 as best we can.

12 BY MS. MAINIGI:

13 Q. Do you agree that the best
14 way, and the most consistent way to
15 communicate to an industry is through
16 written guidance?

17 MR. FINKELSTEIN: Objection.
18 Scope.

19 THE WITNESS: I mean it
20 definitely helps. I don't know if
21 it's the best way to do it. I
22 know when we -- I know when we do
23 conferences, that is pretty --
24 that's pretty helpful, you get

1 face-to-face. Schedule
2 investigations with them. You get
3 to know who the people are at
4 the -- the facility. You build a
5 rapport. You build a working
6 relationship with them.

7 So I don't -- I don't -- I
8 don't know that I can characterize
9 and say that -- that written is
10 the best way.

11 BY MS. MAINIGI:

12 Q. And just to make sure the
13 record from before is clear. To your
14 knowledge, the DEA has not issued any
15 best practices regarding what methodology
16 to use to know your customer for
17 distributors and manufacturers?

18 MR. FINKELSTEIN: Objection.
19 Vague. Mischaracterizes.

20 THE WITNESS: For -- we're
21 just talking specifically about
22 controlled substances, because we
23 did provide it for chemical --
24 chemical handlers.

1 BY MS. MAINIGI:

2 Q. So I'll restate the
3 question.

4 To your knowledge the DEA
5 has not issued any best practices
6 regarding what methodology to use to know
7 your customer to distributors and
8 manufacturers in the controlled
9 substances context?

10 A. Correct.

11 MR. FINKELSTEIN: Objection.
12 Vague. Scope. You can answer.

13 THE WITNESS: Correct,
14 correct.

15 BY MS. MAINIGI:

16 Q. And there's no requirement
17 for distributors and manufacturers to
18 document their "know your customer"
19 process, correct?

20 MR. FINKELSTEIN: Objection.
21 Form.

22 THE WITNESS: There's not a
23 written -- written requirement --
24 regulation or requirement of that.

1 However, if you're going to
2 maintain effective control for
3 diversion, you're going to have to
4 be able -- you're going to have to
5 be able to explain how you made
6 that assessment. Was this --
7 especially in terms of suspicious
8 orders, how you came to the
9 conclusion that this was not a
10 suspicious order. So...

11 BY MS. MAINIGI:

12 Q. Is there a best practice
13 document that was distributed to
14 distributors and manufacturers that says
15 that?

16 MR. FINKELSTEIN: Objection.
17 Vague.

18 THE WITNESS: No.

19 BY MS. MAINIGI:

20 Q. Now, you mentioned in the
21 chemicals context, the DEA has in fact
22 issued guidance on knowing your customer;
23 is that correct?

24 A. Correct.

1 Q. And at a high level, are you
2 able to describe for me the guidance?

3 A. Well, I mean with the
4 chemicals, there's thresholds already
5 built in on what a -- on a retail sale of
6 what a customer can buy specifically of
7 ephedrine or pseudoephedrine on a single
8 transaction, on a monthly transaction.

9 We talk about -- in that
10 guidance, we also talk about forms of
11 payment, are they coming to pick it up.
12 Those are some of the higher level ones.

13 Q. Could the DEA have issued
14 guidance in the controlled substances
15 context for knowing your customer?

16 MR. FINKELSTEIN: Objection.
17 Scope. Calls for speculation.

18 THE WITNESS: I mean I think
19 with the regs and the statute and
20 the guidance that we've given
21 through the 2006, 2007 letters, I
22 think with the conference, or the
23 distributor initiative where we
24 have met with them and we've

1 discussed red flags and gone
2 through it, I think they've been
3 given guidance on this.

4 It's not all inclusive list.
5 It's a list of, you scratch --
6 it's basically this doesn't make
7 sense to me.

8 So I don't know that we can
9 pigeonhole. And I think we've
10 given proper guidance to it.

11 BY MS. MAINIGI:

12 Q. So to be clear, in the
13 chemical context, DEA has issued written
14 guidance on knowing your customer when it
15 comes to chemicals, correct?

16 A. So chemicals, those are also
17 embedded in the regulations too. So it's
18 a reiteration of the regulations
19 themselves, because they are in there as
20 well.

21 Q. So the DEA has in fact
22 issued written guidance on knowing your
23 customer in the chemical context,
24 correct?

1 A. Correct.

2 MR. FINKELSTEIN: Objection.

3 Vague.

4 THE WITNESS: Sorry.

5 BY MS. MAINIGI:

6 Q. The DEA has not issued
7 written guidance elaborating on best
8 practices or methodology for knowing your
9 customer in the controlled substances
10 context, correct?

11 MR. FINKELSTEIN: Objection.

12 Vague.

13 THE WITNESS: I believe --

14 BY MS. MAINIGI:

15 Q. I think that's a yes or no?

16 A. Correct, correct, correct.

17 MR. FINKELSTEIN: No, you
18 can answer the question.

19 THE WITNESS: It is correct,
20 but sitting with them and going
21 over the distributor initiative at
22 the distributor conferences where
23 we've gone over the requirements,
24 what their responsibilities are,

1 and gone through all the red
2 flags, they understand what
3 they -- they understand it.

4 BY MS. MAINIGI:

5 Q. And so you think that you
6 know what the distributors understand?

7 A. No --

8 MR. FINKELSTEIN: Hang on.

9 Objection. Argumentive.
10 Mischaracterizes the witness's
11 testimony.

12 BY MS. MAINIGI:

13 Q. So you think -- was it ever
14 considered by the DEA to issue written
15 guidance in the controlled substances
16 context to know your customer?

17 MR. FINKELSTEIN: Objection.
18 I'm going to instruct you not to
19 answer outside of the scope of
20 your written authorization.

21 THE WITNESS: Yeah based on
22 the advice of my attorney, I can't
23 answer that.

24 MS. MAINIGI: He can't

1 answer yes or no whether it was
2 considered?

3 MR. FINKELSTEIN: You heard
4 my instruction.

5 BY MS. MAINIGI:

6 Q. Your position is,
7 Mr. Prevoznik, that whatever has been
8 said in distributor initiative meetings
9 or industry conferences, is sufficient to
10 advise manufacturers and distributors on
11 best practices for knowing your customer?

12 MR. FINKELSTEIN: Objection.
13 Mischaracterizes the witness's
14 testimony.

15 THE WITNESS: I don't think
16 that's what I said.

17 BY MS. MAINIGI:

18 Q. Is it your position that at
19 distributor initiative meetings and
20 industry conferences that you have laid
21 out DEA's expectations regarding
22 manufacturers and distributors knowing
23 their customer?

24 A. Well, the onus of

1 operating -- designing and operating is
2 upon the registrant. So it's on the
3 manufacturers and distributors, since
4 that's what we're talking about that. So
5 the onus is on them to design it.

6 So if they want to discuss
7 it with us, we have discussed it with
8 them. We've had MOAs with them. We
9 discuss when we go out on our scheduled
10 investigation, so it's not just a
11 conference thing. We've had meetings
12 with them where we talk about different
13 things. And if they have suggestions on
14 things, we listen to it. And if we can
15 implement them, we will.

16 Q. So my question was, is it
17 your position that at distributor
18 initiative meetings and industry
19 conferences, that you have laid out DEA's
20 expectations regarding manufacturers and
21 distributors knowing their customers?

22 MR. FINKELSTEIN: Objection.

23 Asked and answered.

24 THE WITNESS: Yes.

1 BY MS. MAINIGI:

2 Q. And this would be reflected
3 in what documents? Where could we go to
4 find out what those expectations were
5 that DEA laid out?

6 MR. FINKELSTEIN: Objection.
7 Argumentive.

8 THE WITNESS: Well, I mean,
9 they -- they got -- they've had --
10 they've been to the conferences.
11 So if you want to see the
12 PowerPoints from the conferences,
13 you can go to our website. The
14 distributor initiatives, they were
15 given the PowerPoints when they
16 came.

17 They -- you know, they know
18 when we've been out on a scheduled
19 investigation. So they know when
20 we've been out there. It's my --
21 it's our understanding that when
22 we're out there, they document
23 everything that we do and say out
24 there.

1 BY MS. MAINIGI:

2 Q. You think the industry
3 documents it?

4 MR. FINKELSTEIN: Objection.
5 Calls for speculation. Outside
6 the scope.

7 BY MS. MAINIGI:

8 Q. Why not just issue the
9 written guidance?

10 MR. FINKELSTEIN: Objection.
11 Outside the scope.

12 THE WITNESS: I can't answer
13 that.

14 BY MS. MAINIGI:

15 Q. Are you familiar with who
16 Demetra Ashley is?

17 A. Yes.

18 Q. And who is Ms. Ashley?

19 A. Now -- she's retired now.
20 She was our deputy assistant
21 administrator.

22 Q. And she was number two at
23 DEA, essentially, for a period of time?

24 A. Yes.

1 Q. And I think you testified
2 earlier that you reviewed her deposition
3 in preparation for today, correct?

4 A. Correct.

5 (Document marked for
6 identification as Exhibit
7 DEA-Prevoznik-7.)

8 BY MS. MAINIGI:

9 Q. I've put in front of you as
10 Exhibit 7 a statement from Ms. Ashley of
11 her testimony before the Judiciary
12 Committee of the United States Senate.

13 It's for a hearing entitled,
14 "Oversight of the Ensuring Patient Access
15 and Effective Drug Enforcement Act."

16 Her testimony is from
17 December 2017.

18 I'm just going to draw your
19 attention to the very last page and ask
20 you just a couple of questions about one
21 particular sentence.

22 And that is on Page 8 of her
23 testimony, third paragraph. In the
24 context of talking about the opioid

1 crisis Ms. Ashley says as follows:

2 "That being said, it is
3 necessary that we accurately inform
4 manufacturers, distributors, and sellers
5 of what they are expected to do to be in
6 compliance with their regulatory
7 responsibilities."

8 Do you see that?

9 A. Yes.

10 Q. Does the DEA agree with that
11 statement by Ms. Ashley?

12 A. Yes.

13 Q. Now, do you know what the
14 HDA is, or the HDMA, as it used to be
15 known?

16 A. Yes.

17 Q. And what is that?

18 A. It's an association of
19 distributors.

20 Q. And from time to time the
21 HDA or HDMA reached out to the DEA in an
22 effort to sit down and seek further
23 clarification and guidance regarding
24 distributor efforts to prevent diversion,

1 correct?

2 A. Correct.

3 MR. FINKELSTEIN: I know
4 this is one of the plaintiffs'
5 topics. Can you explain to me why
6 this is within the scope of your
7 notice?

8 MS. MAINIGI: It relates to
9 guidance.

10 MR. FINKELSTEIN: To
11 registrants is what your notice
12 says.

13 MS. MAINIGI: Yes.

14 MR. FINKELSTEIN: HDA is not
15 a registrant.

16 MS. MAINIGI: It's made up
17 of registrants.

18 MR. FINKELSTEIN: It's not a
19 registrant. It's not within your
20 notice, you can go because it's in
21 the plaintiffs' notice. But I'm
22 going to control this.

23 MS. MAINIGI: Okay.

24 BY MS. MAINIGI:

1 Q. So HDMA, which as you said
2 was made up of a number of distributors
3 who are registrants, correct?

4 A. Correct.

5 Q. HDMA, and these distributors
6 sought guidance from time to time from
7 DEA regarding their efforts to prevent
8 diversion, correct?

9 A. Correct.

10 Q. And, in fact, HDA sent
11 written communication to the DEA seeking
12 clarification, correct?

13 MR. FINKELSTEIN: Object to
14 the scope. You can answer.

15 THE WITNESS: Yes.

16 BY MS. MAINIGI:

17 Q. Did the DEA ever provide a
18 response to those questions?

19 MR. FINKELSTEIN: Objection.
20 Vague. Vague as to time.

21 THE WITNESS: I don't know
22 what time frame you are talking
23 about.

24 BY MS. MAINIGI:

1 Q. Let me get -- while we are
2 getting that document marked, let me
3 bring you back to Ms. Ashley's testimony,
4 Mr. Prevoznik.

5 Pull up that same page in
6 front of you if you could.

7 A. I -- I just want to make
8 sure. Exhibit 7?

9 Q. I'm sorry?

10 A. 7?

11 Q. Yes. Exhibit 7, please.
12 And Page 8.

13 A. Okay.

14 Q. Do you see the paragraph
15 right above the conclusion?

16 A. As we move forward?

17 Q. Yes.

18 A. Yes.

19 Q. Could you read out loud the
20 first sentence please?

21 A. "As we move forward, we
22 recognize the importance of working with
23 registrants, not just at workshops and
24 conferences, but in writing that they can

1 count on, to provide them all the
2 information and especially the certainty
3 that they need to be in full compliance
4 as they want to be and as we expect them
5 to be."

6 Q. Do you agree with that
7 sentence?

8 A. Yes.

9 Q. Is it fair to say that the
10 general view of DEA is that the
11 distributors would like to be in
12 compliance?

13 MR. FINKELSTEIN: Objection.
14 Vague. Calls for speculation.

15 MS. SINGER: Objection to
16 scope as well.

17 THE WITNESS: Yes. Yes, I
18 believe they do.

19 BY MS. MAINIGI:

20 Q. And certainly as you are
21 aware, from time to time, they have
22 reached out to the DEA seeking
23 clarification and further guidance,
24 correct?

1 MR. FINKELSTEIN: Objection.

2 Vague as to time.

3 THE WITNESS: I'm not -- I'm
4 not sure of what specific topics,
5 if you have a specific topic in
6 mind. But yes, they do reach out.

7 BY MS. MAINIGI:

8 Q. And let's say in this time
9 period that we've been lately talking
10 about, the 2008 to 2013 time period,
11 sometimes when distributors and their
12 trade group have reached out, DEA has not
13 felt that they could provide them with
14 complete answers or clarification to
15 their questions, correct?

16 MS. SINGER: Objection.

17 Vague.

18 THE WITNESS: Could you
19 please repeat that?

20 BY MS. MAINIGI:

21 Q. Sure.

22 In that 2008 to 2013 time
23 period that we've focused on, is it fair
24 to say that when registrants such as

1 distributors and their trade associations
2 have reached out to seek clarification,
3 that sometimes DEA has not been able to
4 provide clarification?

5 A. So in this time frame is
6 2008 to 2013?

7 Q. Correct.

8 A. Which was the time when we
9 were investigating and litigating? Yeah,
10 that -- we -- we did not talk at that
11 point.

12 Q. You did not talk to
13 distributors in the 2008 to 2013 time
14 period generally?

15 A. Well, yeah, I mean up until
16 2010 we were doing the distributor
17 initiative. And then we stopped that for
18 a period because of the litigations and
19 the investigations going on.

20 Q. And so what you did say was,
21 as Ms. Ashley alluded to, you might tell
22 them something at a workshop or
23 conference, correct?

24 MR. FINKELSTEIN: Objection.

1 BY MS. MAINIGI:

2 Q. She references here?

3 MR. FINKELSTEIN: Objection.
4 Vague. And vague as to time.

5 THE WITNESS: That's what it
6 says there, correct. I don't know
7 what exact time frame she's
8 talking about, but yes, that's
9 what it says.

10 BY MS. MAINIGI:

11 Q. But certainly the
12 expectation in 2017 was that the DEA felt
13 it was important to work with registrants
14 and to provide information to them in
15 writing that they could count on,
16 correct?

17 A. That's what it says,
18 correct.

19 Q. And since that time, has
20 that happened?

21 MR. FINKELSTEIN: Objection.
22 Vague.

23 THE WITNESS: Has what
24 happened?

1 BY MS. MAINIGI:

2 Q. Since 2017, has the DEA
3 provided distributors with any additional
4 guidance on suspicious order
5 monitoring --

6 A. I don't --

7 Q. Written guidance.

8 A. Not written guidance that
9 I'm aware of.

10 Q. There was some discussion in
11 the last several years of a modification
12 to the suspicious order regulation,
13 correct?

14 A. Correct.

15 Q. And why was that?

16 MR. FINKELSTEIN: Objection.
17 I'm going to instruct you not to
18 answer, because this was something
19 that we specifically didn't
20 authorize.

21 THE WITNESS: I'm following
22 the instruction of my attorney.

23 BY MS. MAINIGI:

24 Q. Did, in fact, DEA make any

1 proposals outside of DEA to modify the
2 suspicious order regulations in the last
3 several years?

4 MR. FINKELSTEIN: I'm going
5 to instruct you not to answer to
6 the extent that your answer would
7 call for deliberative
8 conversations within DEA that --
9 that were not -- did not result in
10 a final action.

11 THE WITNESS: The only --
12 based on my attorney's advice, the
13 only thing that I can say is that
14 we did provide a tool to the
15 industry back in 2018 to help them
16 with the identified data with
17 ARCOS.

18 BY MS. MAINIGI:

19 Q. And what was that tool that
20 was provided in 2018?

21 A. It was that the -- they
22 could put the pharmacies DEA's
23 registration in it and it would show a
24 number of suppliers of base code.

1 Q. And what would that allow
2 distributors to do?

3 A. That would allow
4 distributors to see how many customers --
5 how many other distributors that were
6 servicing that customer or --

7 Q. And that would allow
8 distributors to, therefore, recognize and
9 have visibility into a customer who was
10 ordering from two or more distributors at
11 one time, correct?

12 A. Yes. But it also --
13 hopefully it would also, because we did
14 run into a situation in which it was --
15 the company had multiple registration,
16 and it showed the number two, but it was
17 actually in fact the same company, it was
18 just different registrants. So it's
19 really just a pointer.

20 Q. But it does have the effect
21 of enhancing distributors anti-diversion
22 efforts, correct?

23 A. Correct.

24 Q. And is that the type of

1 change that distributors had been
2 suggesting for years?

3 MR. FINKELSTEIN: I'm going
4 to interject something for the
5 record because it clarifies my
6 earlier objection. Topic 2 had
7 asked for --

8 MS. MAINIGI: Excuse me.
9 There's not a question pending.

10 MR. FINKELSTEIN: I'm going
11 to make my record. And then you
12 can respond.

13 MS. MAINIGI: You're going
14 to interrupt a different line of
15 questioning to make your record,
16 because you've just now figured
17 out where you need to go in your
18 letter?

19 MR. FINKELSTEIN: As I
20 said --

21 MS. MAINIGI: Okay. Go
22 ahead, David. Let's give you the
23 floor.

24 MR. FINKELSTEIN: Okay.

1 Thank you. You had asked for
2 communications with third parties
3 concerning potential amendments to
4 or updates 1301.74. We had said
5 that we asked you to identify with
6 specificity which communications
7 you wanted.

8 As we received no further
9 clarity on the meaning of third
10 parties, Mr. Prevoznik is not
11 authorized to provide testimony on
12 the aforesaid topic. So that's
13 the basis for my instruction not
14 to answer.

15 MS. MAINIGI: Well, thank
16 you so much.

17 MR. FINKELSTEIN: You're
18 welcome.

19 MS. MAINIGI: Let's go back
20 to the question, Mr. Prevoznik,
21 that was pending when your counsel
22 interrupted.

23 MR. FINKELSTEIN: And --
24 never mind.

1 BY MS. MAINIGI:

2 Q. So the change that was made
3 in -- so, for sake of identification,
4 what you are talking about, what the DEA
5 made available in 2018 was something
6 called ARCOS online reporting?

7 A. No.

8 Q. What was it called?

9 A. It was -- I don't know what
10 we call it to be honest with you. It was
11 a tool enhancement.

12 Q. Okay. So it was a tool
13 enhancement that allowed distributors to
14 have greater visibility in some manner
15 into the scope of where their customers
16 were ordering from?

17 A. Correct.

18 Q. And was this a change that
19 the distributors had been asking for?

20 MR. FINKELSTEIN: Objection.
21 Vague.

22 THE WITNESS: To my
23 knowledge, because I'm the one
24 that suggested it, I am not aware

1 of distributors asking for it at
2 that time.

3 We've always, with our
4 dialogue with the distributors,
5 it's always been, this is our
6 business strategy, protect -- this
7 is proprietary protected. And as
8 an agency, that's how we always
9 treat their -- their data.

10 So it really came to my
11 attention when I moved upstairs to
12 pharmaceutical section, that
13 dealing with a lot of FOIAs and
14 things like that, this might --
15 this might work. So I made the
16 suggestion to Ms. Ashley at that
17 time.

18 BY MS. MAINIGI:

19 Q. And Ms. Ashley followed your
20 suggestion?

21 A. Well, we eventually got it
22 in there, yes. So yes.

23 Q. And is the suggestion that
24 was implemented allowing distributors

1 greater visibility into their customers'
2 ordering, is that something that could
3 have been implemented years earlier?

4 MR. FINKELSTEIN: Objection.
5 Calls for speculation.

6 THE WITNESS: I don't know.

7 BY MS. MAINIGI:

8 Q. Is there any reason that you
9 have to believe that the change that you
10 had effected in 2018 couldn't have been
11 effected in 2012?

12 MR. FINKELSTEIN: Objection.
13 Scope.

14 THE WITNESS: I don't --
15 we've made some vast changes to
16 ARCOS. So the technology today is
17 way different than what it was
18 back then. So that I don't know
19 that it would have been as good
20 back then, but it's certainly
21 something that could have been
22 explored.

23 BY MS. MAINIGI:

24 Q. And was it explored in 2012?

1 MR. FINKELSTEIN: Objection.

2 I'm going to instruction not
3 to answer, to the extent that your
4 answer calls for internal
5 conversations within the DEA.

6 THE WITNESS: Based on that,
7 I'm going to listen to my
8 attorney.

9 BY MS. MAINIGI:

10 Q. You have no reason to
11 believe that this was a proposal or a
12 change that DEA advocated outside of DEA
13 be made prior to 2018, correct?

14 A. I'm sorry. One more time.

15 Q. You have no reason to
16 believe that the DEA advocated for the
17 change that was made in 2018 to be made
18 earlier than 2018 outside of DEA?

19 MS. SINGER: Objection.

20 Scope.

21 THE WITNESS: I'm not sure.
22 I don't know.

23 BY MS. MAINIGI:

24 Q. If HDMA and the distributors

1 sent a letter in 2011 asking the DEA a
2 number of questions, to which they hoped
3 for clarification, I take it your
4 response would be the reason the DEA
5 didn't provide a response was because of
6 litigation?

7 MR. FINKELSTEIN: You can
8 answer the questions. You don't
9 have to accept her answer.

10 MS. SINGER: Objection.
11 Scope.

12 THE WITNESS: I don't think
13 it was just litigation. I think
14 it was ongoing investigations at
15 that point.

16 BY MS. MAINIGI:

17 Q. But because of litigation
18 and ongoing investigations, the DEA did
19 not want to provide distributors with
20 greater clarity to their questions on
21 anti-diversion?

22 MR. FINKELSTEIN: Object to
23 the characterization.

24 And the same instruction

1 that don't answer to the extent
2 that your answer calls for
3 internal deliberative process
4 information.

5 THE WITNESS: I don't know.

6 BY MS. MAINIGI:

7 Q. You don't know any
8 reasons -- excuse me. You don't know any
9 reasons --

10 A. No, I'm agree -- I'm
11 following my attorney's advice regarding
12 internal discussions.

13 MS. MAINIGI: Why don't we
14 take a short break. I think I'm
15 ready to pass this witness.

16 MR. FARRELL: To me?

17 MS. MAINIGI: No. To
18 someone this way.

19 MR. FINKELSTEIN: Five
20 minutes, Counsel. Who is next?

21 THE VIDEOGRAPHER:
22 2:33 p.m., we are off the video
23 record.

24 (Short break.)

1 THE VIDEOGRAPHER: 2:47, we
2 are on the video record.

3 BY MS. MAINIGI:

4 Q. Mr. Prevoznik, just a few
5 more questions from me right now.

6 (Document marked for
7 identification as Exhibit
8 DEA-Prevoznik-8.)

9 BY MS. MAINIGI:

10 Q. I'm going to hand you
11 Exhibit 8. Sorry.

12 A. No problem.

13 Q. And if I could draw your
14 attention -- you're obviously welcome to
15 read the entire thing, but I'm going to
16 really focus on the bottom paragraph on
17 the first page, forward. Just let me
18 know when you've read through it.

19 MR. FARRELL: Since this is
20 an evidentiary deposition and the
21 witness is reading and I'm not
22 taking your time, I'm going to
23 make an objection to this on
24 foundation purposes, and I've

1 asked you to lay a proper
2 foundation before getting into
3 this document.

4 MS. MAINIGI: That would be
5 a form objection. The way we do
6 it is we say, "Objection, form."

7 MR. FULLER: You say we.
8 Who is we?

9 MR. FARRELL: I have
10 transcripts that say otherwise as
11 you'll recall. But I do think a
12 foundation needs to be established
13 or none of this is going to be
14 admissible.

15 Do you agree?

16 MS. MAINIGI: I have no
17 comment, Paul. If -- if you make
18 an objection down the road, that's
19 your prerogative.

20 MR. FARRELL: So you're
21 waiving foundation?

22 MS. MAINIGI: No, I'm
23 absolutely not waiving foundation.

24 MR. FARRELL: That's what I

1 asked --

2 MS. MAINIGI: I'm waiving
3 discussion of it today or I'm
4 deferring discussion of it today.

5 BY MS. MAINIGI:

6 Q. Just let me know when you're
7 ready, Mr. Prevoznik.

8 A. Okay. Which paragraph in
9 particular?

10 Q. Let's just first identify
11 the -- the letter. The letter that is
12 marked Exhibit 8 is an exchange -- well,
13 it's a letter from the DEA and
14 specifically James Arnold from the DEA to
15 Mr. Kevin Nicholson who is at the
16 National Association of Chain Drug
17 Stores, correct?

18 A. Correct.

19 Q. And what is Mr. Arnold's
20 role, or what was Mr. Arnold's role in
21 2018?

22 A. He was the section chief of
23 the policy liaison section.

24 Q. And that was -- that's one

1 of the sections that will, from time to
2 time, have communications with the
3 industry; is that right?

4 A. Correct.

5 Q. And that communication could
6 relate to guidance; is that right?

7 MR. FINKELSTEIN: Objection.
8 Vague.

9 THE WITNESS: I'm not really
10 sure what you mean by the word
11 guidance.

12 BY MS. MAINIGI:

13 Q. Well, guidance related to
14 anti-diversion efforts or anti-diversion
15 regulations.

16 MR. FINKELSTEIN: Objection.
17 Vague.

18 THE WITNESS: I mean, the --
19 the policy section answers a lot
20 of different things. It's not
21 just the anti-diversion stuff.
22 It's all kinds of things.

23 BY MS. MAINIGI:

24 Q. But anti-diversion would be

1 one of the areas that the policy section
2 might provide a response onto third
3 parties?

4 A. Yes.

5 Sorry.

6 Q. And Mr. Nicholson -- excuse
7 me. Mr. Arnold in this letter -- well,
8 let me just draw your attention to -- to
9 the bottom paragraph. Could you read
10 that paragraph out loud, please?

11 A. The one that starts finally?

12 Q. Yes, please.

13 A. "Finally, the DEA has
14 proposed to revise its regulations
15 relating to suspicious orders of
16 controlled substances. The proposed rule
17 defines the term 'suspicious order' and
18 specifies the procedures a registrant
19 must follow upon reviewing such orders.
20 You can monitor the progress of the
21 suspicious orders of the substances" --
22 "of controlled substances proposed rule
23 on the unified agenda located at
24 www.regulations.gov. And the above

1 stated proposal rule has been assigned
2 regulatory identification Number (RIN)
3 1117-AB47.

4 MS. SINGER: Object to this
5 line of questions, because it's
6 outside of the scope for the
7 reasons that the Department of
8 Justice previously offered.

9 MS. MAINIGI: Okay. We
10 believe this line of questioning
11 relates to Topics 2 and 3.

12 But obviously someone else
13 will ultimately decide.

14 BY MS. MAINIGI:

15 Q. So, Mr. Prevoznik, when did
16 the DEA first communicate to the public
17 that there were potential changes that
18 may be coming with respect to its
19 suspicious order regulations?

20 MR. FINKELSTEIN: Hang on.
21 I'm going to instruct you not to
22 answer that question.

23 The basis again is our
24 March 22, 2019, letter where we

1 said he is not authorized to
2 provide testimony on this
3 subtopic.

4 MS. MAINIGI: This relates
5 to Topics 2 and 3. And in
6 particular, guidance. Because if
7 there are changes to guidance,
8 that's relevant. And there have
9 been changes to guidance over the
10 years which we have already
11 discussed in this deposition to
12 date.

13 So I can't control what you
14 do in terms of instructing your
15 witness. But we think it is very
16 much in scope.

17 MR. FINKELSTEIN: You are
18 correct that you can't control
19 what I do as to instructing the
20 witness. We're not going to argue
21 an appeal from our authorization
22 letter right here. Unless you
23 want to.

24 So you can proceed with your

1 questions and I'll instruct
2 appropriately.

3 BY MS. MAINIGI:

4 Q. So, Mr. Prevoznik, when did
5 the DEA communicate to the public for the
6 first time that there were changes that
7 were being considered related to
8 suspicious orders?

9 MR. FINKELSTEIN: Instruct
10 you not to answer.

11 THE WITNESS: I follow the
12 advice of my attorney.

13 BY MS. MAINIGI:

14 Q. Is it fair to say,
15 Mr. Prevoznik, that some of the changes
16 that were being considered would have
17 provided greater definition and -- and
18 greater specificity to the term
19 "suspicious order"?

20 MR. FINKELSTEIN: Calls for
21 speculation. But because it's
22 outside the scope, I instruct you
23 not to answer.

24 BY MS. MAINIGI:

1 Q. Is it further fair to say,
2 Mr. Prevoznik, that the proposed rule
3 would have also offered procedures a
4 registrant, such as a distributor, must
5 follow upon receiving an order that they
6 believe to be suspicious?

7 MR. FINKELSTEIN: Instruct
8 you not to answer.

9 THE WITNESS: Following the
10 advice of my attorney.

11 BY MS. MAINIGI:

12 Q. IS it fair to say that the
13 change in regulation is no longer under
14 consideration by the DEA?

15 MR. FINKELSTEIN: Different
16 objection. Instruct you not to
17 answer to the extent that your
18 answer would call for deliberative
19 communications.

20 THE WITNESS: Could you
21 repeat the question?

22 BY MS. MAINIGI:

23 Q. Is it fair to say that the
24 change in regulations is no longer under

1 consideration by the DEA?

2 MR. FINKELSTEIN: The
3 instruction is, don't testify
4 based on internal DEA
5 communications regarding any
6 possible change in regulation.

7 BY MS. MAINIGI:

8 Q. Now, it looks like from this
9 letter -- oh, I'm sorry, are -- are you
10 not answering the question,
11 Mr. Prevoznik?

12 A. Could you repeat your
13 instruction one more time?

14 MR. FINKELSTEIN: Do you
15 want to repeat the question?

16 MS. MAINIGI: It's in the
17 record.

18 MR. FINKELSTEIN: Without
19 hearing -- without hearing the
20 question back, the witness isn't
21 going to know how to follow my
22 instruction.

23 MR. FARRELL: Do you want me
24 to read it?

1 MS. MAINIGI: If I could ask
2 the court reporter to read it
3 back, please.

4 (Whereupon, the court
5 reporter read back the requested
6 portion of testimony.)

7 MR. FINKELSTEIN: And the
8 instruction is, don't testify
9 based on internal DEA
10 communications.

11 THE WITNESS: I would say
12 no.

13 BY MS. MAINIGI:

14 Q. Mr. Prevoznik, if I go to
15 this website that is referenced in this
16 June 2018 letter, at regulations.gov and
17 put in this regulatory identification
18 number, will I find, to your knowledge,
19 the proposed rule?

20 MR. FINKELSTEIN: Objection.
21 Scope.

22 Yeah. Excuse me.

23 Objection. Scope, calls for
24 speculation.

1 You can answer if you know.

2 THE WITNESS: I don't know.

3 BY MS. MAINIGI:

4 Q. The proposed rule entitled
5 "Suspicious Orders of Controlled
6 Substances Proposed Rule," was that at
7 one time published online and had
8 specifics related to redefinition of the
9 term "suspicious order"?

10 MR. FINKELSTEIN: Instruct
11 you not to answer.

12 THE WITNESS: Following the
13 advice of my attorney.

14 BY MS. MAINIGI:

15 Q. You can't answer if it was
16 online at some point and gave greater
17 specificity to the term "suspicious
18 order"?

19 MR. FINKELSTEIN: We asked
20 you what to prep the witness for.

21 You can answer based on your
22 personal knowledge.

23 THE WITNESS: I'm a little
24 confused, because I thought I

1 answered that one.

2 BY MS. MAINIGI:

3 Q. Let me ask it again. I will
4 endeavor to ask the same question,
5 perhaps just slightly differently. And
6 that is, what was published on the
7 website, did that actually include the
8 specifics of the proposed change in
9 definition to suspicious order?

10 MR. FINKELSTEIN: This is
11 outside the scope of the witness's
12 authorization.

13 But you can answer based on
14 your personal knowledge.

15 THE WITNESS: I don't know.

16 BY MS. MAINIGI:

17 Q. Do you know whether the
18 proposed rule that was online provided
19 specifics as to the procedures a
20 registrant would follow with the
21 modification?

22 MR. FINKELSTEIN: Same
23 objection. Same instruction.

24 THE WITNESS: I don't know.

1 BY MS. MAINIGI:

2 Q. What was perceived to be the
3 need that led to the change in the
4 terminology for suspicious order and the
5 additional procedures for dealing with a
6 suspicious order?

7 MR. FINKELSTEIN: Instruct
8 you not to answer.

9 THE WITNESS: Following the
10 advice of my attorney.

11 MS. MAINIGI: Okay. Well,
12 we will go ahead and move on to
13 the next questioner. We don't
14 agree with your objections on
15 scope. We don't agree with your
16 instructions to the witness not to
17 answer. And we'll consider
18 whether to follow up on that
19 either in the next two days or
20 thereafter.

21 MR. FINKELSTEIN:
22 Understood.

23 MS. MAINIGI: Thank you,
24 Mr. Prevoznik, very much for your

1 time.

2 THE VIDEOGRAPHER: Agree to
3 go off the record?

4 MR. FINKELSTEIN: Yes.

5 THE VIDEOGRAPHER: 2:58. We
6 are off the video record.

7 (Brief pause.)

8 THE VIDEOGRAPHER: 3:03. We
9 are on the video record.

10 - - -

11 EXAMINATION

12 - - -

13 BY MR. EPPICH:

14 Q. Good afternoon,
15 Mr. Prevoznik. My name is Chris Eppich,
16 I represent the McKesson company in
17 this -- in this litigation. I just have
18 a few questions for you about the
19 Controlled Substances Act and the -- and
20 the corresponding regulations. You're
21 familiar with the Controlled Substances
22 Act, aren't you?

23 A. Yes.

24 Q. The CSA -- I'll abbreviate

1 it the CSA. The CSA does not require
2 distributors to report the suspicious
3 orders of other distributors, does it?

4 A. Correct.

5 Q. And the CSA does not require
6 distributors to share information with
7 each other about suspicious orders,
8 correct?

9 A. Correct.

10 Q. Now, similarly, the
11 regulations do not require distributors
12 to report suspicious orders of other
13 distributors, correct?

14 A. Correct.

15 Q. And the regulations do not
16 require distributors to communicate with
17 each other about suspicious orders,
18 correct?

19 A. Correct.

20 Q. In fact, the regulations
21 only apply to the suspicious orders that
22 a distributor receives from its own
23 customers, correct?

24 A. You lost me on the

1 customer --

2 Q. Well, the right --

3 MR. FINKELSTEIN: You can
4 finish your answer. Please do.

5 THE WITNESS: You lost me on
6 where you said that the customer
7 gives you the --

8 BY MR. EPPICH:

9 Q. I'll ask it again.

10 A. Sure.

11 Q. Isn't it true that the
12 regulations only apply to the suspicious
13 orders that a distributor receives from
14 its own customers?

15 A. You still lost me. How is
16 the -- how is the distributor getting --
17 getting the suspicious order from their
18 customer?

19 Q. I'll strike the question.

20 You're generally familiar
21 with distributors' suspicious order
22 monitoring programs?

23 A. Correct.

24 Q. And DEA is aware that the

1 distributors programs, they set a monthly
2 threshold for a customer's controlled
3 substances purchases?

4 MR. FINKELSTEIN: Objection.
5 Calls for speculation.

6 THE WITNESS: To my
7 knowledge, yes.

8 BY MR. EPPICH:

9 Q. And DEA never instructed
10 distributors to set a monthly threshold
11 at a specific level, did they?

12 A. No.

13 Q. DEA never instructed
14 distributors to set monthly thresholds
15 for controlled substances at 8,000 dosage
16 units, did they?

17 A. No.

18 MR. EPPICH: That's all the
19 questions I have for you this
20 afternoon. Let me pass the
21 witness.

22 THE VIDEOGRAPHER: Going off
23 the record, 3:05 p.m. We are off
24 the video record.

1 (Brief pause.)

2 THE VIDEOGRAPHER: 3:08. We
3 are on the video record.

4 - - -

5 EXAMINATION

6 - - -

7 BY MR. O'CONNOR:

8 Q. Mr. Prevoznik, good
9 afternoon. I'm Andrew O'Connor. I
10 represent one of the manufacturers in the
11 case. I appreciate your time today?

12 A. Thank you.

13 Q. I want to pick up where
14 Mr. Eppich left off. Is it fair to say
15 that the Controlled Substances Act does
16 not require manufacturers to report
17 suspicious orders submitted to other
18 manufacturers?

19 A. Manufacturers reporting
20 other --

21 Q. Orders submitted to other
22 manufacturers, correct.

23 A. Well, if there would be one,
24 then they would -- because a manufacturer

1 can sub to another manufacturer.

2 Q. I see.

3 A. So there could be one.

4 Q. Does a manufacturer under
5 the CSA have an obligation to report an
6 order that's placed with another
7 manufacturer?

8 MR. FINKELSTEIN: Objection.

9 Vague, incomplete hypothetical.

10 THE WITNESS: Could you --

11 BY MR. O'CONNOR:

12 Q. Sure. So if you had a
13 situation where Manufacturer A received a
14 suspicious order from Distributor A, is
15 it fair to say that Manufacturer B does
16 not have an obligation to report that
17 order?

18 MR. FINKELSTEIN: Same
19 objection.

20 THE WITNESS: I'm trying to
21 follow your logic on this one.
22 Can you give me -- try one more
23 time.
24

1 BY MR. O'CONNOR:

2 Q. Sure. Manufacturer A
3 receives a suspicious order from
4 Distributor A. Does Manufacturer B, a
5 separate manufacturer, have any duty to
6 report that order from the distributor to
7 the other manufacturer?

8 A. I think I'm getting lost,
9 because I am not understanding the
10 manufacturer getting a suspicious order
11 from a distributor. So is the -- I'm
12 lost on that one.

13 Q. Okay. A minute ago you
14 testified that a distributor does not
15 have an obligation to report the order,
16 the suspicious order of another
17 distributor.

18 Do you recall that?

19 A. Yes, and now that you
20 reminded me, because of what you just
21 asked your first question, I need to
22 clarify that, because you could have a
23 distributor selling to another
24 distributor, which could trigger a

1 suspicious order of that sale.

2 Q. Okay. But assuming in that
3 case that the distributors weren't buying
4 from one another, there is no obligation
5 of a distributor to report the suspicious
6 orders going to all the other
7 distributors, correct?

8 MR. FINKELSTEIN: Objection.
9 Incomplete hypothetical.

10 THE WITNESS: So there's
11 so -- there's so many things --

12 BY MR. O'CONNOR:

13 Q. All right. Well, we'll move
14 on --

15 A. I apologize. It's --
16 it's --

17 Q. -- we'll circle back. We'll
18 move on for now.

19 Are you familiar with the
20 term "closed system of distribution"?

21 A. Yes.

22 Q. What does that mean to you?

23 A. That is the system in which
24 Congress enacted for the authorized

1 handling of controlled substances. So it
2 requires DEA -- DEA registration;
3 everybody needs to be registered. And
4 then the rules and the regulations that
5 promulgate that system, so that it -- it
6 can account for all the different
7 transactions that are within the system.
8 So manufacturer to distributor, I mean
9 there's always going to be a different
10 circle. But if I could just go straight
11 down the line.

12 Q. Sure.

13 A. It would be manufacturer to
14 distributor to -- to retail level. And
15 then it stops at the retail level.

16 Q. Okay. So in general terms,
17 the closed system of distribution
18 includes manufacturers who then sell to
19 distributors who then sell to pharmacies?

20 A. Correct. Retail would be
21 pharmacies. You have some practitioners
22 buying, it could be teaching
23 institutions, hospitals, narcotic
24 treatment programs.

1 Q. And under the CSA, the
2 registrant's responsibilities depend in
3 part on where they sit within that
4 distribution chain, correct?

5 MR. FINKELSTEIN: Objection.
6 Vague.

7 THE WITNESS: I'm not sure
8 what exactly you're asking.

9 BY MR. O'CONNOR:

10 Q. Well, a manufacturer has
11 certain obligations that are different
12 from, for example, a pharmacist. Is that
13 fair?

14 A. Correct.

15 Q. Okay. So whereas a
16 pharmacist might have to have some
17 obligations with respect to particular
18 prescriptions, a manufacturer does not
19 have an obligation to review or -- or
20 monitor particular prescriptions,
21 correct?

22 A. The -- the prescriptions
23 from a pharmacy?

24 Q. Correct.

1 A. No, they don't.

2 Q. Okay. Are you familiar with
3 C.F.R. -- 21 C.F.R. 1301.74?

4 A. Yes.

5 Q. That's the suspicious order
6 monitoring regulation?

7 A. Yes.

8 Q. Fair if I call it that?

9 Okay. With respect to
10 manufacturers, what is a suspicious order
11 for controlled substances?

12 A. Well, I mean, 823, the
13 statute -- statutory requirement that you
14 have to have effective controls against
15 diversion. So it starts with that. Then
16 you go to 1301.74. They, as -- as
17 manufacturer and the distributor, would
18 have the same requirements of designing
19 and building a system to identify
20 suspicious orders. So it's incumbent
21 upon a manufacturer to build that system.

22 Q. So with respect to
23 manufacturers, what is a suspicious order
24 for controlled substances?

1 MR. FINKELSTEIN: Objection.
2 Vague.

3 THE WITNESS: Well, I mean
4 if you go to 1301.74(b), it would
5 still -- you would still apply the
6 same sales of orders, including
7 unusual size, orders deviating
8 substantially from a normal
9 pattern or would result in unusual
10 frequency. Because
11 manufacturers -- its --
12 manufacturers also distribute to
13 the practitioner level as well.

14 So, so if they are selling
15 to a practitioner, not that
16 they -- they -- they would --
17 that's their customer. So they
18 would have to have the same
19 effective controls as the
20 distributor would, because it's
21 going to the retail level. So
22 there's -- there's that part.

23 There's also the part of --
24 there' -- is their product going

1 straight to the distributor level?
2 Is it going straight to the
3 pharmacy level? Is it going to
4 another -- a repackager,
5 re-labeler?

6 I mean, manufacturer has
7 various options. So it's -- it's
8 going to have to set a system that
9 can identify, detect, a suspicious
10 order. So whatever realm
11 that's --

12 BY MR. O'CONNOR:

13 Q. So --

14 A. -- where it goes.

15 Q. -- would -- would a
16 definition of a suspicious order change
17 depending on what type of customer the
18 manufacturer is selling to?

19 A. I don't know that it's --
20 it's just ironclad that it's the customer
21 you're selling to. It -- it's -- it's
22 the gambit of unusual size. It's the
23 same if it's going into, say, one
24 particular state and they have

1 information regarding that. Then they
2 would.

3 Q. You mentioned orders of
4 unusual size, frequency, or deviating
5 substantially from normal pattern. I
6 want to spend some time on those.

7 With respect to orders that
8 are placed to manufacturers, what
9 constitutes an order of unusual size in
10 the DEA's view?

11 A. Well, as you know from the
12 statute regulations, the onus is on the
13 registrant to identify it. It's not for
14 us to identify it. It's for the
15 registrant to identify it.

16 So, I don't know the -- the
17 situation. I mean it would be all
18 hypothetical situations that I would be
19 proposing. And I'm not sure that I can
20 cover every single hypothetical for you.

21 Q. So 21 C.F.R. 1301.74 is a
22 regulation, correct?

23 A. Correct.

24 Q. DEA promulgated that

1 regulation?

2 A. Correct.

3 Q. And that regulation includes
4 the term "suspicious orders," does it
5 not?

6 A. Correct.

7 Q. Okay. So I'm asking you as
8 a representative of DEA, the meaning of
9 suspicious orders.

10 MR. FINKELSTEIN: That's a
11 different question.

12 THE WITNESS: Yeah, that's
13 a -- so you want to know what a
14 suspicious order is?

15 BY MR. O'CONNOR:

16 Q. Let's start there and then
17 we can get back to unusual size.

18 A. Okay. So a suspicious order
19 is an order which the order recipient
20 detects through its suspicious monitoring
21 program an order that the -- the
22 detection provides a reason or reasons
23 that the sale or the transaction may
24 be -- I'm sorry, may be diverted into the

1 other -- other legitimate -- other than
2 the legitimate channels of scientific,
3 medical or industry channels.

4 Q. Okay. How would a
5 manufacturer tell whether an order
6 indicates a reason or reasons that the
7 sale or transaction may be diverted into
8 other than legitimate channels?

9 A. Well, I mean we are familiar
10 with one case with chargeback data where
11 the manufacturer knew their customer.
12 They also knew their customers' customer,
13 where the product was going. And they
14 were able to ascertain from that, from
15 their own data, that quite -- over --
16 almost 60 percent of their product was
17 going into one state.

18 MR. FARRELL: I'm sorry,
19 I -- I couldn't hear you.
20 Which -- which manufacturer did
21 you say?

22 THE WITNESS: I didn't.

23 MR. FARRELL: Oh.

24 MR. FINKELSTEIN: If you can

1 try to speak up a little bit.

2 THE WITNESS: I'm sorry.

3 MR. FINKELSTEIN: Big room.

4 BY MR. O'CONNOR:

5 Q. So let's go back to the --
6 the issue of unusual size.

7 How does the manufacturer
8 determine whether an order is of an
9 unusual size as that term is used under
10 the DEA regulations?

11 A. Well, I mean, again, these
12 are -- this is going to be hypothetical,
13 because I don't know where this is --
14 where this sale is taking place. Is it
15 going to a practitioner? Is it going
16 directly to the pharmacy? Is it going to
17 another distributor? Is it going to
18 another manufacturer?

19 Q. Well --

20 A. Because unusual size could
21 be -- it's going to be different if it
22 goes to a practitioner. It may be -- I
23 mean, again, I'm speculating, so I don't
24 know.

1 Q. So let's say it's an order
2 placed by a distributor to a
3 manufacturer. How does a manufacturer go
4 about determining whether an order is
5 unusually -- unusually size -- unusual in
6 size?

7 A. Well, I mean, these are --
8 this is not an inclusive list. So it
9 could be one of them. It could be a
10 number of them. It could be patterns of,
11 you know, this product has -- I mean, I
12 don't know which products we're talking
13 about. But this product, which has had
14 very little movement all of the sudden
15 explodes and is -- you know, how did that
16 happen?

17 So those would be kind of
18 questions that I would want to look at.
19 I would want to look at, you know, who --
20 who are their customers and try to get a
21 better understanding of what are they
22 doing with the product.

23 Q. So to make this a little
24 more concrete, let's say we had an order

1 from a distributor to a manufacturer for
2 oxycodone. How big of an order would be
3 an order of unusual size?

4 A. I wouldn't know. I can't
5 give you a figure on that. I don't know
6 the distributors' ranges of how far they
7 extend out to their customer base. It
8 could be multiple states. It could be
9 one state. It could...

10 Q. Fair to say that you can't
11 determine whether an order is unusually
12 large by simply looking or considering
13 one factor?

14 MR. FINKELSTEIN: Objection.
15 Vague.

16 THE WITNESS: Well, again if
17 it goes to a practitioner, it
18 probably could, or a pharmacy it
19 probably could. But --

20 BY MR. O'CONNOR:

21 Q. And let's say it went to a
22 practitioner. How would you know what's
23 unusually large?

24 A. Well, you would want -- part

1 of your figuring it out would be -- is
2 what is the percent that other
3 practitioners of similar specialty who
4 are ordering, how much do they order. I
5 mean, there's a variety of different
6 things that you could look at to try to
7 make that determination. I don't think
8 you can just take the number alone and
9 say, "Oh, that's big."

10 Q. So with respect to orders
11 placed by distributors to manufacturers
12 how can a manufacturer tell if an order
13 deviates substantially from a normal
14 pattern?

15 A. So this is a -- is this
16 sales to a manufacturer to a distributor?

17 Q. Correct.

18 A. So you would want to look at
19 the history of what is that relationship
20 and what has been a typical order. And
21 it could potentially trigger, that seems
22 a little odd. So let me at least -- what
23 it does is just detects and says, all
24 right, this is something that we probably

1 need to follow up on.

2 Q. Okay. And how can you tell
3 if an order is a typical order versus one
4 that deviates substantially from a normal
5 pattern?

6 A. Well, I apologize. It's --
7 I don't know if you can say what the
8 difference is a typical order and that.
9 What you have is you have a history of
10 what are -- what are the sales to that
11 distributor. So you would start with
12 that. But as you -- as you -- as the
13 customers -- you know, what questions are
14 you asking the distributors? Are you
15 asking them for their customers? And,
16 you know, who are they selling to?

17 And then you can look at
18 newspaper articles and see the overdose
19 deaths. You can see this is affecting
20 these communities that these product,
21 your products, are going into, because
22 that distributor is putting them in
23 there. So you would have to start asking
24 those questions.

1 Q. But when a manufacturer
2 receives an order from a distributor, how
3 do you tell whether that particular order
4 deviates from a normal pattern, even
5 looking at the sales history to that
6 distributor?

7 A. I'm not sure I'm following.

8 Q. Well, I'm just asking you,
9 DEA has imposed this obligation on
10 manufacturers. And I'm wondering whether
11 DEA has a position on how a manufacturer
12 should determine whether a particular
13 order that comes into it from a
14 distributor, deviates from a normal
15 pattern?

16 A. Well, I mean, you can go
17 back to the internet days when it was --
18 the pattern was all of the sudden
19 products that were skyrocketing to the
20 millions and hundreds of thousands that
21 were never there.

22 Q. So you're saying if a
23 product was not being purchased at all
24 previously and then skyrocketed --

1 A. I'm not saying not at all.
2 But if it's -- if it's not been used
3 much, and then all of the sudden it takes
4 off.

5 Q. Okay. And if it does take
6 off, is that enough to conclude that the
7 product is being diverted?

8 A. I don't think it's enough to
9 conclude that it's diverted, just based
10 on that. But it should be enough to make
11 it a suspicious order, to at least report
12 it.

13 Q. Okay. And how big an
14 increase do you have in mind when you say
15 skyrocket?

16 A. I don't have a number in
17 mind.

18 Q. It sort of depends on the
19 situation?

20 A. It depends on the situation,
21 yeah.

22 Q. All right. How about with
23 respect to unusual frequency? When a
24 manufacturer receives an order from a

1 distributor, how does it determine
2 whether the order is one of unusual
3 frequency?

4 A. Well, again, are they
5 ordering more and more? I mean, again,
6 it depends on the situation. Again,
7 these are not -- not one particular
8 thing. It could be two of them, it could
9 be three of them. It could be any
10 information that you have obtained that
11 has and shows or that indicates that your
12 product may be being diverted, then you
13 have the responsibility to guard that
14 from doing that. So that would trigger a
15 suspicious order.

16 Q. So fair to say whether an
17 order is of an unusual frequency requires
18 some -- some judgment?

19 A. Yes.

20 Q. It's fair to say that it's
21 in the eye of the beholder?

22 A. I don't think it's in the
23 eye of the beholder because it's -- the
24 data is going to show you what is going

1 on. So the data is going to tell you,
2 oh, I might need -- this might -- this
3 doesn't make sense. This sort of makes
4 sense.

5 Q. But as you sit here today,
6 you can't tell us exactly how frequent an
7 order would have to be for it to be
8 unusually frequent?

9 A. No, I can't.

10 Q. Has the DEA provided any
11 written guidance to manufacturers
12 regarding how to identify suspicious
13 orders?

14 A. I mean, we've gone through
15 the Rannazzisi letters of 2006 and 2007.

16 Q. Okay. Aside from the
17 Rannazzisi letters of 2006 and 2007, has
18 the DEA provided manufacturers with any
19 other guidance on how to determine
20 whether an order is suspicious?

21 A. I know we've met with some
22 of them, with -- in part of the
23 distributor initiative, we actually met
24 with some of the manufacturers. The

1 guidance was provided to them, very
2 similar to what the distributor
3 initiative was.

4 Q. How many manufacturers did
5 you meet with?

6 A. I don't recall off the top
7 of my head.

8 Q. Okay. More than ten? Less
9 than ten?

10 A. I would say -- I'd be
11 guessing on that. I think it's less than
12 ten.

13 Q. Okay. Fair to say not every
14 manufacturer was met with?

15 A. Correct.

16 Q. And aside from those 2006
17 and 2007 letters from Joe Rannazzisi, was
18 there any other written guidance provided
19 to manufacturers regarding how to
20 identify a suspicious order?

21 A. No.

22 Q. If a registrant had a
23 question about how to comply with its
24 obligations under the suspicious order

1 monitoring regulation, what part of DEA
2 should it take that question to?

3 A. It depends -- I mean, we
4 have contacts within the field offices.
5 So you can start with the field office.

6 Q. Okay.

7 A. If the field office felt
8 that this rose, they would instruct --
9 they would instruct the manufacturer to
10 write to the policy section of
11 headquarters.

12 Q. Okay. Are you aware of any
13 instances in which the manufacturer -- a
14 manufacturer did write to the policy
15 section requesting guidance on suspicious
16 orders?

17 A. I am not aware of it.

18 Q. Okay. You -- you mentioned
19 that the manufacturer might also go to
20 the field office. Is the field office
21 the -- the DEA location that's in the
22 manufacturer's geographic area? Is
23 that -- is that what that refers to?

24 A. Yeah, our -- our area of

1 responsibility.

2 Q. Okay. When a -- a DEA
3 diversion investigator, for example,
4 provides instructions to a registrant in
5 its geographic region, does the DEA
6 expect the registrant to follow that
7 instruction?

8 A. I don't know what the
9 instruction is, but, yeah, I would -- I
10 would think so.

11 Q. And if a manufacturer asked
12 a question of someone in the DEA field
13 office and -- and they received an
14 answer, would it be fair for that
15 registrant to rely on what the field
16 office said?

17 MR. FINKELSTEIN: Objection.
18 Vague.

19 THE WITNESS: Again, I don't
20 know exactly what the question
21 you're asking is, so...

22 BY MR. O'CONNOR:

23 Q. When someone in the DEA
24 field office tells a registrant

1 something, does the DEA expect the
2 registrant to ignore that?

3 A. No.

4 Q. The DEA would expect the
5 registrant to -- to comply with the
6 instructions from the field office,
7 correct?

8 A. Yeah, again I -- I don't
9 know what the issue is that you're
10 talking about, so...

11 Q. Okay. Has the DEA ever
12 issued a model suspicious order
13 monitoring policy?

14 A. No. We have the regulations
15 and the statute as well as the guidance
16 and the letters.

17 Q. And when you say the
18 letters, you mean the 2006 and 2007
19 letters?

20 A. Right. And -- and the
21 initiatives, if we sat down with you. It
22 would also be guidance in there as well.

23 Q. Okay. Why hasn't the DEA
24 issued a model suspicious order

1 monitoring policy?

2 MR. FINKELSTEIN:

3 Objection --

4 MS. SINGER: Objection.

5 Beyond the scope.

6 MR. FINKELSTEIN: Objection.

7 Instruct you not to answer to the

8 extent that your answer calls for

9 internal DEA communications.

10 THE WITNESS: Could you

11 repeat the question?

12 BY MR. O'CONNOR:

13 Q. Sure.

14 Why hasn't the DEA issued a
15 model suspicious order monitoring policy?

16 A. Based on the advice of my
17 attorney, I can't answer that.

18 Q. Earlier today you mentioned
19 scheduled investigations. Remind me
20 again what a scheduled investigation is.

21 A. Schedule investigation
22 are -- it's basically our work -- a
23 diversion investigator's work plan. So
24 they will be assigned certain registrants

1 that we will go out and inspect their
2 facility, their registration.

3 Q. And is that inspection or
4 visit different from what might be
5 referred to as a DEA audit or are they --

6 A. They're the same.

7 Q. The same. Got it.

8 And during a scheduled
9 investigation or audit, does the DEA
10 review a registrant's written policies?

11 A. Their protocols?

12 Q. Yes.

13 A. Yes.

14 Q. And if the DEA has concerns
15 about those policies, does it raise those
16 concerns with the registrant?

17 MS. SINGER: Objection.

18 Calls for speculation.

19 THE WITNESS: To my -- yes,
20 they do.

21 BY MR. O'CONNOR:

22 Q. Does DEA make -- make
23 determinations about whether particular
24 orders are suspicious if they are asked

1 to by registrants?

2 MR. FINKELSTEIN: Objection.

3 Vague.

4 THE WITNESS: I'm not sure I
5 understand.

6 BY MR. O'CONNOR:

7 Q. If a registrant came to
8 someone at DEA and said, is this
9 particular transaction suspicious, would
10 the DEA, as a matter of policy and
11 procedure, provide them an answer to that
12 question?

13 A. The statute and the regs
14 require the registrant to identify it as
15 suspicious. It's not us to do it.
16 It's -- it's incumbent upon the
17 registrant to make that determination.

18 Q. So --

19 A. We don't have all the
20 information.

21 Q. So that scenario, the DEA
22 would refuse to make a determination as
23 to whether the order was suspicious or
24 not, correct?

1 MR. FINKELSTEIN: Objection.

2 Mischaracterizes.

3 THE WITNESS: Could you
4 repeat that?

5 BY MR. O'CONNOR:

6 Q. Sure.

7 So in the scenario, the DEA
8 would refuse to make a determination as
9 to whether a particular order was
10 suspicious or not, correct?

11 A. Again, it's the registrants
12 that has to make that determination,
13 whether it's suspicious or not.

14 If -- if we're going to make
15 that determination, then investigation
16 has led us down that road that we will --
17 we will -- we will look at all the orders
18 and see if we can determine.

19 But even if we determine,
20 it's still going to be ultimately up to
21 the jury and -- to make the decision.

22 Q. But if a registrant came to
23 you today and said I am trying to decide
24 whether this order is suspicious, am I

1 correct that the DEA's policy is that the
2 DEA will not provide a yes or no answer
3 to that question?

4 MR. FINKELSTEIN: Objection.
5 Incomplete hypothetical. But you
6 can answer.

7 THE WITNESS: I would be
8 extremely concerned if you as a
9 registrant came to me and asked me
10 to make that determination.
11 Because you are basically telling
12 me that you -- you do not have the
13 ability to effectively -- to
14 maintain effective guards against
15 diversion if you're coming to us
16 with that hypothetical. Which
17 would be grounds for us to revoke
18 your registration.

19 BY MR. O'CONNOR:

20 Q. So the DEA -- the DEA's
21 position is that if a registrant comes to
22 the DEA with a question about whether an
23 order is suspicious, that may be grounds
24 to start an investigation of that

1 registrant?

2 MR. FINKELSTEIN: Objection.
3 Mischaracterizes the witness's
4 testimony.

5 THE WITNESS: No, that's not
6 what I -- if that's how it --
7 that's not what I said.

8 BY MR. O'CONNOR:

9 Q. Okay. So just to be clear,
10 if the DEA receives a question from a
11 registrant regarding a particular order
12 and the registrant wants DEA's input on
13 whether or not it's suspicious, would the
14 DEA answer that question?

15 MS. SINGER: Objection.
16 Asked and answered.

17 MR. FINKELSTEIN: Vague.
18 You can answer.

19 THE WITNESS: I thought I
20 just answered it.

21 BY MR. O'CONNOR:

22 Q. What is the answer?

23 A. The answer, is I would be
24 very concerned that if you're coming to

1 us to ask us if this is a suspicious
2 order, you no longer have the -- you are
3 no longer maintaining effective --

4 Q. So --

5 A. You're not guarding -- you
6 are not guarding against diversion if
7 you're asking us to make that
8 determination of that.

9 If you're asking us to
10 review -- to review your system, that's a
11 different question. But if you're coming
12 to us, asking us to make the
13 determination, you're pretty much -- to
14 me, you're pretty much telling us, we
15 don't know what we're doing.

16 Q. What -- what if the
17 registrant made a determination, just
18 asked DEA, did we get it right, would
19 your answer change?

20 MR. FINKELSTEIN: Objection.
21 Vague.

22 THE WITNESS: I'm -- these
23 are all hypotheticals. I don't --
24 I'd have to -- it would be more

1 than just this -- this. I
2 wouldn't make an assessment based
3 on that.

4 BY MR. O'CONNOR:

5 Q. So you can't say what your
6 answer -- what the DEA's answer would be
7 in that situation?

8 A. Well, I mean, we would look
9 into all the different factors. Again if
10 you're coming to us and asking us if it's
11 a suspicious order, again we would be
12 wondering, do you really have control
13 over what you're doing.

14 Q. You spoke earlier today
15 about the training DEA diversion
16 investigators receive. Does that
17 training include instruction on
18 suspicious order monitoring?

19 A. The training where?

20 Q. The training that diversion
21 investigators receive?

22 A. At Quantico, in the basics
23 school or where?

24 Q. Let me ask you that in a

1 different way. What training do
2 diversion investigators receive with
3 respect to suspicious order monitoring?

4 MR. FINKELSTEIN: Objection.
5 Scope.

6 You can answer if you know.

7 THE WITNESS: That would be
8 part of the law and the
9 recordkeeping -- recordkeeping
10 curriculum. That would be part of
11 that.

12 BY MR. O'CONNOR:

13 Q. Just to be clear, is it the
14 case that diversion investigators do
15 receive training with respect to
16 suspicious order monitoring?

17 A. Yes. Sorry.

18 MR. FINKELSTEIN: Scope.

19 But...

20 THE WITNESS: Sorry.

21 BY MR. O'CONNOR:

22 Q. I'm going to turn back to
23 another topic you spoke about earlier
24 today referred to the distributor

1 initiative.

2 What, in DEA's view, is the
3 distributor initiative?

4 A. Back in 2005 when we
5 started, that was when we were addressing
6 the internet. So it went from the
7 regional local diversion issues to a more
8 national -- not a more -- I mean it went
9 national.

10 So the distributor
11 initiative was to be able to sit down
12 with the distributors and go over their
13 own data with them to discuss, A, their
14 requirements; B, their duties; and the
15 data that showed abnormalities so that
16 they would have a better understanding of
17 what was going on with the internet.

18 Q. Was there any manufacturer
19 initiative around the same time?

20 A. No.

21 Q. I want to turn to what's
22 already been marked as Exhibit 5. It's
23 the 2007 Rannazzisi letter.

24 Is this letter in front of

1 you the first guidance provided to
2 manufacturers regarding the obligation to
3 monitor suspicious orders?

4 A. Could I refresh my memory?

5 Q. Sure.

6 MR. FINKELSTEIN: There is
7 an index in the front.

8 THE WITNESS: Yeah. You
9 said written guidance?

10 BY MR. O'CONNOR:

11 Q. Yes. Actually, I apologize.
12 I said the first guidance.

13 A. First what?

14 Q. First guidance, not limited
15 to written guidance.

16 A. I mean, we had seminars
17 earlier that we had talked to them.

18 Q. And which seminars were
19 those?

20 A. The one in particular that
21 I'm referring to was the one in San
22 Antonio, Texas, April 7th and 9th of
23 1987. It says "Seminar Report,
24 Controlled Substance Manufacturers and

1 Wholesale Seminar."

2 Q. And just for the record,
3 what document are you using to refresh
4 your recollection?

5 MR. FINKELSTEIN: Don't take
6 it out.

7 THE WITNESS: Oh. I mean, I
8 read it to you. It was "Seminar
9 Report, Controlled Substance
10 Manufacturers and Wholesalers
11 Seminar," San Antonio, Texas,
12 April 7th and 9, 1987.

13 BY MR. O'CONNOR:

14 Q. Between 1987 and the 2007
15 Rannazzisi letter, did DEA provide
16 manufacturers with any other guidance
17 regarding the obligation to monitor
18 suspicious orders?

19 A. I mean, there were industry
20 meetings. I don't know the dates of
21 them, besides that one, that also went
22 over that information.

23 I'm still looking for the
24 2006 letter.

1 Q. And what were manufacturers
2 told during those industry meetings
3 regarding their obligation to monitor
4 suspicious orders?

5 A. Again, it was the statute
6 and the regulations.

7 Q. They were informed of the
8 statute and the regulations?

9 A. Yeah.

10 Q. Were they provided any
11 further detail about how to identify a
12 suspicious order during those seminars?

13 A. I think it was -- it was a
14 reminder of the, you know, the -- being
15 able to identify the order before being
16 consummated as a purchase.

17 Q. But the DEA didn't provide
18 any further detail about how the
19 manufacturer should go about identifying
20 a suspicious order, correct?

21 A. That's my understanding.

22 Q. And when you say it was a
23 reminder of being able to identify the
24 order before being consummated as a

1 purchase, when were manufacturers
2 informed of that?

3 A. Like I was explaining in
4 this San Antonio document, there's a
5 section on Page 10 called "Excessive
6 Order Monitoring Programs." And it says,
7 "First, any system must be capable of
8 both detecting individual orders which
9 are suspicious, or orders which are" --
10 become suspicious over a time due to
11 frequency, quantity, or pattern.

12 The national wholesaler -- I
13 forget what the title -- National
14 Wholesale Druggist Association had a
15 system they were pushing. It says, "The
16 NWDA system, for example, provides an
17 excellent lookback or trend system, but
18 the ability to identify one-time
19 suspicious orders should not be
20 overlooked as an element of a program.

21 Q. I apologize if I missed it.
22 Where in there did it say that suspicious
23 orders must be reported before they're
24 shipped?

1 A. Well, that goes back to the
2 statute where it says maintaining
3 effective controls over diversion.

4 Q. But the statute doesn't say
5 that suspicious orders need to be
6 reported before they're shipped, does it?

7 A. Not in that specific
8 language. But it does -- it does
9 indicate that if you're going to have an
10 effective system to detect it, because
11 you're not maintaining -- you're not
12 maintaining the effective -- you're not
13 maintaining effective control against
14 diversion if you're constantly selling
15 product.

16 Q. But you would agree with
17 me -- go ahead.

18 A. Sure. Go ahead.

19 Q. You would agree with me that
20 the statute itself does not contain the
21 express instruction that a registrant
22 should hold an order and not ship it if
23 it determines it to be suspicious,
24 correct?

1 A. Correct.

2 Q. And that explicit
3 instruction is not found in the document
4 you are currently looking at either,
5 correct?

6 A. Well, it does continue with,
7 "Another area of issue was whether DEA
8 would take action against a registrant
9 which reported an order and then shipped
10 it. DEA pointed out that the company is
11 still responsible, under the regulations,
12 for acting in the public interest.
13 Requiring the order" -- "Reporting the
14 order does not in any way relieve the
15 firm from the responsibility for the
16 shipment."

17 Q. Okay. That does not say
18 that suspicious orders need to be
19 reported before they're shipped, does it?

20 A. Well, it doesn't say that
21 specifically. But it says reporting
22 orders does not in any way relieve the
23 firm for the responsibility for the
24 shipment. So again, it's maintaining

1 effective controls against diversion.

2 Q. Just for the clarity of the
3 record, I think I'd like to mark --

4 MR. O'CONNOR: Should I mark
5 the whole binder? Let's go ahead
6 and mark the whole binder. What
7 are we on? Eight? Nine?

8 (Document marked for
9 identification as Exhibit
10 DEA-Prevoznik-9.)

11 MR. FINKELSTEIN: And just
12 for the record, we are talking
13 about Tab 4 of what's been now
14 marked as Exhibit 9.

15 MR. O'CONNOR: Thank you.

16 BY MR. O'CONNOR:

17 Q. Since 2007 and the letter
18 from Joe Rannazzisi, has the DEA provided
19 manufacturers with any further written
20 guidance regarding the obligation to
21 monitor suspicious orders?

22 A. No.

23 Q. Is every order that's
24 unusually large -- strike that.

1 Does every order that's
2 unusually large necessarily lead to
3 diversion?

4 A. I have no idea.

5 MS. SINGER: Objection.

6 Scope.

7 THE WITNESS: I have no idea
8 what you mean by unusually large.

9 BY MR. O'CONNOR:

10 Q. Okay. As the term
11 "unusually large" is used in the
12 suspicious order monitoring regulation,
13 are orders that are unusually large
14 necessarily diverted?

15 A. Well, for example, a bottle
16 of 100 Vicodin from a manufacturer to a
17 vet, is that unusually large?

18 Q. Is it?

19 A. I don't think it's unusually
20 large, but it would raise my eyebrows of
21 why would -- why would a vet be ordering
22 that bottle when they know that the
23 toxicity to cats and dogs would kill
24 them. So I don't think you can just look

1 at a number and say that's too big.

2 MR. O'CONNOR: Whoever is on
3 the phone needs to go on mute.

4 MR. FINKELSTEIN: Whoever is
5 on the phone please mute your
6 phone.

7 BY MR. O'CONNOR:

8 Q. Before we get back to my
9 question, I just want to be clear.
10 Are -- are vets required to obtain a DEA
11 registration before they order controlled
12 substances?

13 A. Yes.

14 Q. And the DEA issues some
15 veterinarians registrations to allow them
16 to purchase controlled substances?

17 A. Correct.

18 Q. Okay. I do -- I do want to
19 get back to my original question though,
20 which was, is an order that is unusually
21 large, does that order necessarily lead
22 to diversion?

23 MR. FINKELSTEIN: Objection.
24 Vague.

1 THE WITNESS: It may or
2 may -- it may or may not.

3 BY MR. O'CONNOR:

4 Q. Would the same be true of an
5 unusually frequent order?

6 MR. FINKELSTEIN: Same
7 objection. You can answer.

8 THE WITNESS: Correct. It
9 may or may not.

10 BY MR. O'CONNOR:

11 Q. And the same would be true
12 of an order that deviates substantially
13 from the normal pattern?

14 MR. FINKELSTEIN: Same
15 objection. You can answer.

16 THE WITNESS: Correct. It
17 may or may not.

18 BY MR. O'CONNOR:

19 Q. Okay. And putting that
20 together, that means that not every
21 suspicious order leads to diversion,
22 correct?

23 MR. FINKELSTEIN: Objection.
24 Scope. You can answer.

1 THE WITNESS: Could you
2 please repeat that?

3 BY MR. O'CONNOR:

4 Q. Not every suspicious order
5 leads to diversion, correct?

6 A. Correct.

7 Q. I want to talk a little bit
8 about how suspicious order reports are --
9 are used within DEA.

10 Is it fair to say that most
11 suspicious order reports are submitted to
12 field offices?

13 A. I would say based on the
14 fact that the big three are filing
15 electronically, I would say the majority
16 electronically.

17 Q. When an order or when
18 suspicious order reports are filed
19 electronically, does that mean they are
20 filed with headquarters?

21 A. Yes. On the Legacy and the
22 vetted system.

23 Q. Okay. And do registrants
24 that are not reporting electronically to

1 headquarters, do they report to their
2 field offices as specified in the
3 regulation?

4 A. Correct.

5 Q. Who at DEA has access to the
6 SORs available in the Legacy and vetted
7 systems at headquarters?

8 A. Diversion investigators --

9 MR. FINKELSTEIN: Hang on.

10 Vague as to time. You can answer.

11 THE WITNESS: Diversion
12 investigators. The ARCOS
13 targeting analysis group, they
14 also have it. The field
15 investigators have it. Some of
16 our special agents in tactical
17 diversion squads have acces to it.

18 But primarily it's the
19 diversion investigators that have
20 it.

21 BY MR. O'CONNOR:

22 Q. When you say diversion
23 investigators, do you mean the diversion
24 investigators in the field offices?

1 A. Correct.

2 Q. Had they always had access
3 to the electronic Legacy and vetted
4 systems at DEA?

5 A. The vetted system started in
6 2017. So they've had access to that.

7 Previous to that they've not
8 always had access to it.

9 Q. So before 2017, diversion
10 investigators in the field didn't have
11 access to the centrally stored suspicious
12 order reports at DEA headquarters?

13 MR. FINKELSTEIN: Objection.
14 Mischaracterizes.

15 THE WITNESS: They -- they
16 would get quarterly reports sent
17 out from the -- from headquarters
18 to the field. Like that.

19 BY MR. O'CONNOR:

20 Q. So before 2017, the
21 diversion investigators in the field
22 would receive reports of the SORs that
23 were submitted once a quarter. Do I have
24 that right?

1 MR. FINKELSTEIN: Objection.
2 Mischaracterizes.

3 THE WITNESS: It would be --
4 it would be like on a quarterly
5 basis they would get it.

6 BY MR. O'CONNOR:

7 Q. Okay.

8 A. But that wasn't all the
9 time.

10 Q. Okay. So just so the record
11 is clear, how often would the diversion
12 investigators in the field receive
13 suspicious order reports from
14 headquarters before 2017?

15 MS. SINGER: Objection.

16 Asked and answered.

17 THE WITNESS: It varied over
18 a certain period of time. But it
19 was -- when they did get it, it
20 was on a quarterly basis.

21 BY MR. O'CONNOR:

22 Q. And those were the -- of the
23 suspicious orders that were reported in
24 the prior quarter?

1 A. No. It's the -- it's
2 everything has been reported.

3 Q. Everything that's been
4 reported over the past three months,
5 correct?

6 A. No. It's been reported for
7 the year.

8 Q. Okay. So once a quarter the
9 DIs would receive suspicious orders that
10 had been reported prior to that date?

11 A. So, there were periods where
12 they would get a quarterly report. So it
13 would be either FY first quarter of
14 whatever year. Then it would be the
15 second quarter. Then it would be the
16 third quarter. But that varied in some
17 years.

18 Q. I want to talk about the
19 reports that were submitted directly to
20 field offices.

21 The report -- the suspicious
22 order report is submitted to the field
23 office. Is it necessarily sent up to
24 headquarters?

1 A. From the field?

2 Q. Yeah.

3 A. No.

4 Q. Are those reports sent to
5 other field offices?

6 A. They would -- they would
7 send it to the AOR that that registrant
8 was being reported as a suspicious -- if
9 it wasn't in their AOR, which is the area
10 of responsibility, it would be sent to
11 that other office.

12 Q. Okay. Got it. So if a
13 report was sent to the field office in
14 New York that report would not be sent to
15 a field office in Florida, correct?

16 A. So the man -- the -- I'm
17 sorry, the manufacturer in New York is
18 reporting to the New York office?

19 Q. Correct.

20 A. The New York office would
21 be -- send the Florida -- the SORs that
22 are identified to down to the Florida
23 office, whichever office it is. So it's
24 Miami, West Palm, Tampa.

1 MR. FINKELSTEIN: Counsel,
2 can I ask for a comfort break
3 pretty soon?

4 MR. O'CONNOR: Sure. We can
5 take one now.

6 MR. FINKELSTEIN: Okay.
7 Thank you.

8 THE VIDEOGRAPHER: 4:00 p.m.
9 We are off the video record.

10 (Short break.)

11 THE VIDEOGRAPHER: 4:17. We
12 are on video record.

13 BY MR. O'CONNOR:

14 Q. Welcome back. Before the
15 break you had mentioned that the field
16 offices receive quarterly reports of the
17 suspicious order reports that are
18 submitted to headquarters. Do I have
19 that --

20 A. The Legacy.

21 Q. -- right?

22 Was there ever any time when
23 the field offices did not receive those
24 reports from headquarters?

1 A. There were periods where
2 they did not.

3 Q. Okay. What were those
4 periods?

5 A. It was when Kyle Wright was
6 in charge of that unit.

7 Q. Okay. Do you remember
8 approximately when that was?

9 A. I don't -- I don't know the
10 years.

11 Q. But during the years while
12 Kyle Wright was there, the suspicious
13 order reports that were submitted to
14 headquarters were not sent out to the
15 field offices?

16 A. No. There would be -- they
17 would go out sporadically, quarterly, so
18 you could have a period where they
19 weren't sent out, and you would have a
20 period where they were sent out.

21 Q. Okay. But they did not go
22 out quarterly?

23 A. Typically when they went
24 out, they went out quarterly when they

1 did go out. When they didn't go out, it
2 would be the next, you know, whatever,
3 that Kyle sent out.

4 Q. Okay. So fair to say that
5 there were longer periods, six months or
6 a year where the reports didn't go out?

7 A. I -- I don't recall if it
8 was that long. But there were periods
9 where they did not go out.

10 Q. All right. I'd like to go
11 back to Exhibit 4, which you should still
12 have a copy of.

13 A. Which one is that?

14 Q. Exhibit 4.

15 A. Got it.

16 Q. And do you recognize this
17 document?

18 A. Yes.

19 Q. What -- what is it?

20 A. It's the report to the U.S.
21 Attorney General regarding the suspicious
22 orders task force under the Comprehensive
23 Methamphetamine -- Methamphetamine
24 Control Act of 1996.

1 Q. Okay. I'm going to direct
2 your attention to the page that ends in
3 2212. It's towards the beginning.

4 A. I'm sorry. What was the
5 last number?

6 Q. 2212.

7 A. Okay.

8 Q. And specifically, the first
9 full paragraph that begins, "The task
10 force concluded that a single listing of
11 meaningful numerical parameters would be
12 difficult for the majority of registrants
13 which do not have highly automated
14 computer systems" -- "computer ordering
15 and tracking systems, the indicators
16 contained in Appendix A" -- exhibit --
17 and it's hard to read -- "represent
18 expanded guidance to be considered."

19 Then it continues. "For
20 the" -- "For the segments of industry who
21 have highly automated ordering and
22 tracking systems, the task force
23 recommends a system which starts with
24 quantifiable parameters which track

1 frequency of orders, deviation from prior
2 orders, and size of orders. See Appendix
3 A, Exhibit 2."

4 When this document talks
5 about recommending a system, they are
6 talking about a suspicious order
7 monitoring system, correct?

8 A. Right. For chemicals, List
9 1 chemicals.

10 Q. Okay. But it is a
11 suspicious order monitoring system,
12 agree?

13 A. Yes.

14 Q. Okay. And it says, "See
15 Exhibit" -- I'm sorry. Strike that.

16 It says, "See Appendix A,
17 Exhibit 2."

18 Let's turn there.

19 A. Okay.

20 Q. And I can tell you the
21 number at the bottom ends in 2247.

22 A. Okay. 2247?

23 Q. 2247.

24 A. Okay.

1 Q. So that sentence referring
2 to suspicious order monitoring refers to
3 this exhibit.

4 Could you please read the
5 first five lines starting with,
6 "Exhibit 2."

7 A. Under terms and definition
8 or above?

9 Q. Above.

10 A. "Suspicious order reporting
11 system of 1998 for use in automated
12 tracking systems. The current
13 calculation being used for List 1
14 chemicals and Schedule II through V
15 controlled substances."

16 Q. Okay. So according to that
17 title, the calculation that's discussed
18 in this exhibit is being used for
19 Schedule II through V controlled
20 substances, correct?

21 MR. FARRELL: Objection.

22 THE WITNESS: That's what it
23 says. Yes, that's what it says.

24 BY MR. O'CONNOR:

1 Q. And looking down to Number
2 4, where it says "Note:" Could you
3 please read that sentence?

4 A. "Note: Factor equals 3 for
5 C-II and C-III controlled substances
6 containing List 1 chemicals and eight for
7 C-III and V" -- I don't know what --
8 "controlled substances and noncontrolled
9 OTC product containing List 1 chemical
10 items."

11 Q. So this document again is
12 discussing controlled substances, not
13 just list chemicals, correct?

14 MR. FARRELL: Objection.
15 Misstates. Foundation.

16 BY MR. O'CONNOR:

17 Q. You can answer the question.

18 A. Yes. It's talking about
19 both. It's listed -- controlled
20 substances with listed chemical,
21 controlled substances and noncontrolled.

22 Q. Okay. Take a look at Item
23 5. Could you please read that paragraph.

24 A. Sure. "At the end of each

1 month, a report will be transmitted to
2 DEA, separate reports for List 1
3 chemicals and Schedules II through V
4 controlled substances. Of all purchases
5 of List 1 chemicals and/or C-II through V
6 controlled substances and
7 List-1-containing OTC items by any
8 customers, any customer whose purchase
9 quantities exceed the parameters above,
10 any two consecutive months or in three,
11 if any, moving six-month period."

12 Q. So this document, labeled
13 Exhibit 2 to the suspicious order task
14 force report is discussing a system that
15 pertains to controlled substances,
16 correct?

17 A. Yes. That's what it's
18 talking about.

19 Q. Okay. You can put that
20 aside. Mr. Prevoznik have you heard the
21 term "know your customers' customers"
22 before?

23 A. Yes.

24 Q. When was the first time you

1 heard that term?

2 A. It had to do with the
3 Mallinckrodt investigation.

4 Q. Okay. Do you remember
5 approximately what year you heard the
6 term?

7 A. It was, I believe -- can I
8 look at my report?

9 Q. Sure.

10 A. Actually I have to correct
11 myself. It was actually during the
12 briefing with Mallinckrodt when we met
13 with them back in 2011.

14 Q. Okay. And before that
15 briefing in 2011, you had not heard the
16 term "know your customers' customer"
17 before, correct?

18 A. Yes, correct.

19 Q. What do you understand know
20 your customers' customer to mean?

21 A. So what I -- what I know it
22 to mean is that you have who your
23 customer is that you sell to, but you
24 have information regarding customers that

1 they're selling to. Selling or filling
2 prescriptions to. So it's any
3 information, data, could be newspaper
4 articles. It could be whatever, that if
5 you have data that shows that additional
6 customer, that's what that is. So that
7 would be knowing your customers'
8 customer.

9 Q. So it means knowing about
10 the customers who are purchasing product
11 from your customers; is that fair?

12 A. It would be who you're
13 selling to, and then their customers.

14 Q. Does the DEA have a position
15 as to whether manufacturers are obligated
16 to know their customers' customers?

17 A. The statute requires to
18 maintain safe -- effective controls over
19 diversion. And 1301.71, right here --
20 sorry. 1301.71(a), just the first
21 sentence, "All applicants and registrants
22 shall provide effective controls and
23 procedures to guard against theft and
24 diversion of controlled substances."

1 Q. But neither the statute nor
2 the regulation says explicitly that
3 manufacturers need to know their
4 customers' customers, do they?

5 A. It does not say that
6 explicitly. But it does say that you
7 need to guard against diversion.

8 Q. Has the DEA ever provided
9 guidance to the industry in writing
10 informing registrants that they are to
11 know their customers' customers?

12 A. Not that I'm aware of.

13 Q. Has DEA provided any other
14 kind of guidance, besides written
15 guidance, informing manufacturers of any
16 duty to know their customers' customers?

17 A. Well, again it comes down to
18 what information you have. So if you
19 have that information, you have the duty
20 to protect and guard against the
21 diversion.

22 So if you have that
23 information, you're to guard against
24 diversion of controlled substances.

1 Q. But to my question, has the
2 DEA ever provided any kind of guidance to
3 manufacturers informing them that they
4 were to know their customers' customer?

5 A. No, not to my knowledge.

6 Q. Okay. Let's talk for a
7 minute about ARCOS.

8 Generally speaking, what
9 sorts of information does ARCOS contain?

10 A. ARCOS contains the
11 manufacturers and distributors that are
12 to report all transactions for
13 Schedule I, Schedule II, Schedule III
14 narcotics, and GHB, and manufacturers
15 also have reported -- additional
16 reporting requirements for some
17 psychotropics.

18 Q. Okay. Would ARCOS contain
19 all of the distributions of prescription
20 opioids by manufacturers to distributors?

21 A. So the transactions for
22 manufacture -- yes, manufacturer to a
23 distributor? Yes.

24 Q. Would ARCOS contain all the

1 distributions of prescription opioids
2 from distributors to pharmacies or other
3 retail outlets?

4 A. For those items, yes.

5 Q. Does ARCOS data provide any
6 details about those transactions, like
7 the amount, the recipients --

8 A. Yes, it tracks the quantity.
9 It has the DEA number of the registrant
10 that -- whether it's a sale. It could be
11 a sale, it could be a purchase. It could
12 be a disposition of, you know, getting
13 wasted. Any transaction that -- that
14 could fall within the system that --
15 that's trackable, that would be in there,
16 for those items.

17 Q. Okay. Through ARCOS, can
18 DEA see the type of medication that's
19 being purchased?

20 A. Well, it's in there by NDC
21 number.

22 Q. Okay. And the NDC number
23 would -- would allow the DEA to determine
24 which product we are talking about?

1 A. Correct.

2 Q. So whether that was a -- the
3 DEA would know whether it was a oxycodone
4 5-milligram tablet, for example?

5 A. Correct.

6 Q. That level of detail?

7 A. Yes.

8 Q. Okay. And the DEA receives
9 that information for each tablet that the
10 manufacturers sell to distributors,
11 correct?

12 A. Each tablet?

13 Q. Yes.

14 A. It's by bottle size, because
15 NDC code also has the bottle size within
16 it.

17 Q. Got it. So -- so the DEA
18 can see each and every bottle that's
19 shipped between a manufacturer and a
20 distributor?

21 A. As long as that's what they
22 are reporting, yes.

23 Q. Okay. And through ARCOS,
24 DEA can also see each and every bottle of

1 opioids that's transmitted from a
2 manufacturer -- I'm sorry. Strike that.

3 And through ARCOS, DEA can
4 see each and every bottle of opioids
5 that's transferred from a distributor to
6 a pharmacy for example, correct?

7 A. Correct.

8 Q. And they'll know the
9 location of that pharmacy?

10 A. Correct.

11 Q. Do they have the address for
12 the pharmacy?

13 A. Yes. It's linked to the DEA
14 registration.

15 Q. Okay. So through ARCOS, the
16 DEA has precise information about how
17 much of certain products is being shipped
18 to which geographic areas, correct?

19 A. Correct.

20 Could I get a clarification
21 on what time frame you're talking about?

22 Q. Sure. So I would say 1996
23 to the present. Does the answer change
24 at all during that time period?

1 A. Well, I just -- as I
2 explained earlier this morning, that when
3 it was on the mainframe, there was a
4 delay of -- of reporting. We were
5 limited to a million transactions a
6 night. It could only be one at night.

7 Q. Okay.

8 A. So --

9 Q. So remind me during which
10 period the mainframe was causing this
11 issue?

12 A. I mean, that's how it's been
13 since it started -- well, it started on
14 paper. So we had -- we still have people
15 that -- we still have registrants that
16 are reporting in paper to us.

17 And then it went to magnetic
18 tapes. And it went to discs, and
19 spreadsheets. We've slowly evolved into
20 joining the technology world so that now
21 we have ARCOS online. We have EDI which
22 went into effect in 2004 which took the
23 magnetic tapes out.

24 But again, went on -- when

1 we were on the mainframe, we were limited
2 to only be able to download at night.
3 And the cutoff was a million
4 transactions. That's just the way the
5 system worked.

6 Q. Okay. You mentioned that
7 caused some delays?

8 A. It wouldn't -- you -- it
9 would -- you know, I mean you are talking
10 millions and millions of transactions,
11 either monthly or on a quarterly basis.
12 So it's going to take us a while to
13 process it, do -- do the Q&A on it. If
14 there's errors, we have to reach back out
15 to the registrant, say here, you need to
16 fix your errors. So then, those errors
17 wouldn't get fixed until the next time
18 they reported. So yes, there was a
19 delay.

20 Q. How much of a delay are we
21 talking about?

22 A. It depended. It depended if
23 the registrant fixed the errors. Was it
24 monthly, quarterly. If they didn't fix

1 it, you'd have to go back out to them,
2 say did you fix it.

3 Q. With respect to the delays
4 caused by the mainframe's processing
5 limitations, did that delay things by
6 days, weeks?

7 A. Oh no, you're talking
8 months.

9 Q. Months. Okay. And once
10 that information was processed what
11 happened to it?

12 A. What do you -- what do you
13 mean --

14 MR. FINKELSTEIN: Objection.
15 Vague.

16 THE WITNESS: What do you
17 mean by what happened to it?

18 BY MR. O'CONNOR:

19 Q. What would DEA do with the
20 information once it was done processing
21 through the mainframe?

22 A. Like I -- like I said
23 earlier this morning, it's used for UN
24 reporting. It's used for quotas. It's

1 used for law enforcement. It's used for
2 regulatory -- when you work with state
3 regulatory boards, you share information
4 with them. If we're working on cases
5 regarding the diversion of controlled
6 substances. We use it for trending.

7 It's used for -- researchers
8 often use a lot of the data. They use
9 the reports that are -- the summary
10 reports that we post online.

11 We use it to corroborate
12 investigations. We use it to -- for
13 targeting, like oh here is -- here is a
14 potential target. We use it in a variety
15 of different ways.

16 Q. Did the delays you spoke of
17 give the DEA any concern about its
18 ability to use that data effectively to
19 discharge its obligations?

20 MR. FINKELSTEIN: Objection.
21 Vague.

22 THE WITNESS: Well, you're
23 saying excessive purchases so that
24 was even -- that was more

1 up-to-date for us. So we looked
2 at that. That's why we went
3 through that stuff.

4 BY MR. O'CONNOR:

5 Q. But did the delays give you
6 any concern about DEA's ability to do its
7 job?

8 MR. FINKELSTEIN: Objection.
9 Vague.

10 THE WITNESS: No. We -- we
11 do our job.

12 BY MR. O'CONNOR:

13 Q. Okay. Getting back to the
14 analysis of the ARCOS data. Is there a
15 particular unit within DEA that's charged
16 with analyzing ARCOS data?

17 A. So there's actually two
18 units. There's the input side. They
19 actually deal with the down -- you know,
20 upload from the registrants so there's
21 constant communication with them whether
22 regarding errors or, you know, trying to
23 fix some of the data that was submitted.
24 We don't change the data.

1 It's always the registrant has -- changes
2 the data. We don't -- we don't change
3 it.

4 And then the output side
5 would be the targeting group. So there's
6 QCs on the input side and there's also
7 QCs on the out -- output side.

8 Q. With respect to the
9 targeting group, what sort of analysis
10 does it perform on the ARCOS data?

11 A. Trends. They support case
12 investigations, doing charts, graphs.
13 They'll -- they can show the comparison
14 of what the national average is, what the
15 state average and compare that with the
16 registrant itself.

17 Q. And they can see that
18 information for -- for every registrant?

19 A. Well, if it's an ARCOS
20 reportable item. You don't see
21 everything -- all you see is the ARCOS
22 reportable stuff. You don't see
23 non-ARCOS stuff.

24 Q. But the sort of trends

1 analysis you're talking about, they have
2 the ability to -- to look at data from
3 every registrant that makes ARCOS
4 reports, correct?

5 A. The only thing -- if they
6 make it an ARCOS report, correct.

7 Q. What was the purpose of that
8 unit doing those kinds of trend analyses,
9 for example?

10 A. Well, case support, when we
11 do presentations, whether it's part of
12 the distributor initiative, when we sit
13 down with the companies' own data, they
14 pull the data and put it in charts and
15 show us and provide all those graphs for
16 us. We use them in our presentations
17 when we were talking to the registrant
18 community, whether it's at a distributor
19 conference or if it's when we're, you
20 know, meeting with the manufacturers,
21 going over quotas and ARCOS with them,
22 we'll show them graphs and stuff from
23 that.

24 We also -- I mean, case

1 specifically we'll do whatever the
2 attorney or the investigators need for
3 their case to support it.

4 Q. Does the DEA use ARCOS data
5 to generate leads for investigations?

6 A. It can be.

7 Q. Without getting into any
8 details, can you think of occasions where
9 an analysis of ARCOS data led the DEA to
10 initiate an investigation?

11 MR. FINKELSTEIN: Don't talk
12 about any non-public ones.

13 THE WITNESS: So I could say
14 yes.

15 BY MR. O'CONNOR:

16 Q. Okay. Fair enough. And
17 roughly how many people within DEA are
18 involved in the type of analysis of ARCOS
19 data that you were just talking about?

20 A. So right now on the input
21 side we have four program analysts. And
22 then on the output side, we have six.

23 Q. Okay. And the six people on
24 the output side, is dealing with the

1 ARCOS data their full-time job?

2 A. Yes.

3 Q. Okay. Do they receive any
4 sort of training before taking on the
5 role of analyzing ARCOS data?

6 MR. FINKELSTEIN: Objection.
7 Scope.

8 THE WITNESS: Yes.

9 BY MR. O'CONNOR:

10 Q. And in your view, are they
11 fully qualified to be effectively
12 analyzing ARCOS data?

13 MR. FINKELSTEIN: Objection.
14 Scope. You can answer.

15 THE WITNESS: Yes.

16 BY MR. O'CONNOR:

17 Q. Okay. Changing gears a
18 little bit, have you ever heard of the
19 term "chargeback"?

20 A. Yes.

21 Q. When did you first hear that
22 term?

23 A. Through credit cards and
24 stuff like that, chargeback.

1 Q. Okay. Did you -- when did
2 you first hear the term chargeback in
3 connection with pharmaceuticals?

4 MR. FINKELSTEIN: Hang on.
5 Are you asking him in his personal
6 capacity?

7 MR. O'CONNOR: I'm asking
8 him as DEA.

9 MR. FINKELSTEIN: When was
10 the DEA first aware of chargeback?

11 THE WITNESS: I don't know.
12 I don't know.

13 BY MR. O'CONNOR:

14 Q. How about in your personal
15 capacity?

16 A. Well, all right, I don't
17 know if this -- because I can answer
18 both.

19 Q. Okay.

20 A. But I don't know that that's
21 the initial stage in which we learned
22 about chargeback data. But there was a
23 point in the early 2000s where we were
24 using ChoicePoint which is some of us --

1 it was ChoicePoint or SearchPoint. So
2 that was data that was being sold from
3 pharmacies.

4 Q. So what is ChoicePoint data?

5 A. So it would be pharmacy data
6 that the pharmacists was selling through
7 this company and then we tried -- we had
8 a contract with them. We were -- we were
9 told that we were going to be able to see
10 a certain percentage of the prescriptions
11 that were filled, controlled substances
12 that was going to be filled.

13 We never, ever saw what they
14 promised. So that contract did not last
15 very long. I would say maybe three
16 years.

17 Q. Was SourcePoint different
18 from ChoicePoint?

19 A. No. I think they were the
20 same company, but it was the same.

21 Q. And when you indicate that
22 they didn't provide what you thought they
23 would, what was missing?

24 MR. FINKELSTEIN: We're well

1 outside the scope.

2 But you can answer if you
3 know.

4 THE WITNESS: They were
5 telling us that we would see a
6 certain percentage of what was
7 being done out there. And it was
8 pretty quick that we saw we were
9 not getting what they said.

10 BY MR. O'CONNOR:

11 Q. To your knowledge, did
12 these -- did the ChoicePoint data involve
13 chargebacks at all?

14 A. I just understood it as they
15 were getting the -- the pharmacies were
16 selling the data to them to...

17 Q. Okay. What is the DEA's
18 understanding of a chargeback?

19 A. Well, my understanding of it
20 is that you're getting -- the customer is
21 getting a discount price. And in
22 exchange for that discount price you're
23 getting data back from that customer. So
24 your customer's customers --

1 Q. Okay. What is that data --

2 A. I'm sorry. Customer's
3 customer.

4 Q. Your customer's customer.

5 A. Right.

6 Q. So what role, if any, do
7 chargebacks play in suspicious order
8 monitoring?

9 A. Well, I think it goes
10 directly back to maintaining effective
11 controls over diversion. So if you know
12 your customer's customer is doing
13 something wrong, then you have the
14 obligation and the requirement to keep
15 effective controls over controlled
16 substances.

17 So it's not to be diverted.
18 So if you know that, that it's not for
19 legitimate medical purpose, then you know
20 that, and that's -- you have to take the
21 steps to do that.

22 Q. How does a manufacturer tell
23 if its customer's customer is doing
24 something wrong?

1 MR. FINKELSTEIN: Objection.

2 Vague. Calls for speculation.

3 THE WITNESS: Could you
4 repeat it, please.

5 BY MR. O'CONNOR:

6 Q. Yeah. How does a
7 manufacturer tell if a customer is, in
8 your words, doing something wrong?

9 I'm sorry. Strike -- strike
10 that.

11 How does a manufacturer tell
12 if its customer's customer is, in your
13 words, doing something wrong?

14 A. Well, as I had mentioned
15 earlier, the one investigation that we
16 did, it was -- that registrant told us,
17 we can see exactly where our stuff is
18 going, not just to the distributor. We
19 can see where it's going down into the
20 pharmacy area, to the pharmacies. And it
21 went into a state where it was less than
22 6 percent of the population at 60 percent
23 of the product that they made. Oxy 30s
24 was all going into that state. So that's

1 a little hard to...

2 Q. And to be clear, how would
3 the manufacturer know that a particular
4 customer's customer was doing something
5 wrong?

6 A. Well, I mean they sold it --
7 they sold the data that showed who was
8 filling the prescriptions, you know,
9 which doctor was prescribing, they would
10 show that. So if you see, it's just one
11 group of -- one pain clinic of one
12 doctor, whether it's at the pharmacy or
13 in Florida where it was the physicians
14 themselves, you would know that there's a
15 problem.

16 Q. When you say they sold the
17 data who showed who was filling the
18 prescriptions, who is "they"?

19 A. So the discount price. So
20 they're offered the discount price. But
21 they had to get data to them in order to
22 get the discount price. If they didn't
23 get the discount price -- if they didn't
24 get the data, then they didn't get the

1 discount price, so your customer would be
2 cut off, because the customer didn't want
3 to do that.

4 Q. So I'm a little bit
5 confused.

6 So if -- who sold the data
7 to whom in this scenario?

8 MR. FINKELSTEIN: Objection.
9 Mischaracterizes.

10 THE WITNESS: I cannot -- I
11 would like to refer, to refresh my
12 memory.

13 BY MR. O'CONNOR:

14 Q. Okay. And you're referring
15 to the binder that's marked as Exhibit 9?

16 A. Yes, yes. And in
17 particular --

18 MR. FINKELSTEIN: Either Tab
19 11 or Tab 12.

20 THE WITNESS: Tab 11.
21 Mallinckrodt distributor briefing.
22 This was a briefing held at DEA
23 headquarters on August 23rd, 2011.

24 Page 2. Do you have it?

1 BY MR. O'CONNOR:

2 Q. Yeah.

3 A. It says, "Ms. Duft explained
4 the cash-back system which allows
5 Mallinckrodt to view who their customers
6 are selling to and to what products they
7 are selling. Ms. Duft stated
8 Mallinckrodt has been reviewing this
9 system since last fall, though it's been
10 available to them for several years." So
11 they've had -- they've had the data for a
12 few years.

13 Q. At any point before that
14 time, had anyone at DEA ever told a
15 manufacturer that it should review
16 chargeback data?

17 MR. FINKELSTEIN: Objection
18 to the scope.

19 Industrywide guidance was
20 the authorization, but you can
21 answer if you know.

22 THE WITNESS: I don't know.

23 BY MR. O'CONNOR:

24 Q. Just to be clear, at any

1 point before that time, had the DEA ever
2 issued any industrywide guidance
3 indicating that manufacturers should
4 review chargeback data?

5 A. Not to my knowledge.

6 Q. Earlier you mentioned
7 something about prescription data.
8 Chargeback data doesn't involve
9 prescription data, does it?

10 A. It depends what data -- for
11 SearchPoint and ChoicePoint data that the
12 pharmacies were selling to it.

13 Q. But SearchPoint data was not
14 chargeback data, correct?

15 MR. FINKELSTEIN: Scope.

16 THE WITNESS: It was an
17 exchange of money for their data,
18 so...

19 BY MR. O'CONNOR:

20 Q. Is DEA aware of whether
21 chargeback data provides information on
22 every sale of the Schedule I and II
23 opioids?

24 MS. SINGER: Objection.

1 Scope.

2 MR. FINKELSTEIN: Scope.

3 THE WITNESS: Schedule I?

4 BY MR. O'CONNOR:

5 Q. Schedule II and III.

6 A. I -- could you repeat the
7 question?

8 Q. Yeah. Sure. I'm sorry, I
9 did say Schedule I. Strike that. I'll
10 ask a new question.

11 Is the DEA aware whether
12 chargeback data provides information on
13 every sale of Schedule II and
14 Schedule III opioids?

15 A. I don't know that.

16 Q. Is DEA aware whether
17 chargeback data provides information
18 regarding every sale?

19 MR. FINKELSTEIN: Scope. If
20 we don't get to something that's
21 within his authorization pretty
22 quick, I'm going to start
23 instructing him not to answer.

24 But you can answer that

1 question.

2 THE WITNESS: I don't know.

3 BY MR. O'CONNOR:

4 Q. So let me get to the -- let
5 me get to the scope issue.

6 Does -- does DEA believe
7 that reviewing chargeback data is part of
8 the purported obligation to know one's
9 customer's customer?

10 A. DEA believes that if you
11 have the data and it shows it, then you
12 need to take effective means to stop
13 diversion.

14 Q. When you say shows it,
15 what -- what do you mean exactly?

16 A. Well, if it -- if it's an
17 indicator that -- that things may be
18 diverted out of the legitimate channels
19 into the illicit market, then you should
20 be report -- reporting that as
21 suspicious.

22 Q. In the context of chargeback
23 data, what's an indicator that things may
24 be diverted?

1 A. It depends what date --
2 what's in the dataset that you have. We
3 don't see everything that's in there. So
4 I -- you -- you have the data, so...

5 Q. DEA analyzes ARCOS data,
6 correct?

7 A. Correct.

8 Q. And ARCOS data has all
9 transactions of certain substances,
10 correct?

11 A. For the ARCOS reportable
12 data, yes. It does not have all the
13 non-ARCOS reportable stuff. So if your
14 chargeback data includes other
15 information in there such as the trinity
16 or the holy trinity of the cocktails that
17 are out there, and that information that
18 you have shows that, that is -- that is
19 not taking effective control safeguarding
20 from diversion.

21 Q. Well, what do you mean by
22 "the holy trinity"?

23 A. So the holy trinity, the
24 cocktail of that is oxycodone, an

1 oxycodone product, a benzo, and a muscle
2 relaxer.

3 Q. Okay. Outside of the
4 example that chargeback data might
5 indicate that combination, are there any
6 other indicators in chargeback data that
7 might suggest diversion?

8 MR. FINKELSTEIN: Objection.
9 Scope.

10 THE WITNESS: Again, I'm not
11 sure exactly what data you're
12 looking for. But you might see
13 within that data somebody
14 self-prescribing. You may see a
15 prescriber that's prescribing to
16 family members.

17 BY MR. O'CONNOR:

18 Q. And when you say prescribing
19 to family members, that would be based on
20 looking at the prescription?

21 A. No. As I started with my
22 statement, I don't know exactly what data
23 you are looking for, but if that data is
24 in there, those are some of the things

1 that I would be looking for. I would be
2 looking for somebody that's
3 self-prescribing, prescribing for family
4 members. Those are -- those are
5 indicators or red flags of potential
6 diversion.

7 Q. Outside of self-prescribing,
8 are there any other factors in DEA's view
9 that would -- would suggest diversion
10 when examining chargeback data?

11 MR. FINKELSTEIN: Objection.
12 Scope.

13 This is the last one outside
14 the authorization I'm going to
15 allow.

16 MR. O'CONNOR: Well, to --
17 to be clear, he testified that
18 this was part -- reviewing
19 chargeback data was part of the
20 purported obligation to know your
21 customers' customer. The
22 authorization clearly allows
23 questioning around the know your
24 customers' customer obligation.

1 BY MR. O'CONNOR:

2 Q. Do you need the question
3 back?

4 A. No.

5 Another example would be --
6 again, I don't know exactly what the data
7 that you have. But if the data in there
8 is showing people driving long distances
9 from Kentucky and New Jersey and
10 Tennessee, and coming down to Florida,
11 that's -- to see their doctor to fill the
12 prescription there.

13 You could also see where the
14 prescriber -- I mean, again, I don't know
15 what data you are exactly looking at, but
16 if you had data that shows how the
17 distance between a prescriber and a
18 pharmacy -- this is the only pharmacy
19 within 200 miles that's filling at, all
20 indicators of diversion.

21 Q. Okay. As you sit here
22 today, are there any others that you can
23 think of that you haven't mentioned so
24 far?

1 A. If it was fresh in the
2 morning, I could probably keep going.

3 Q. But as you sit here now?

4 A. Not right now.

5 MR. FINKELSTEIN: Speaking
6 of which, if we could take our
7 last break pretty soon?

8 MR. O'CONNOR: Sure. We can
9 take a break.

10 MR. FINKELSTEIN: Can we
11 make it quick?

12 MR. O'CONNOR: Certainly
13 try.

14 THE VIDEOGRAPHER: 4:58. We
15 are off the video record.

16 (Short break.)

17 THE VIDEOGRAPHER: 5:11. We
18 are on video record.

19 BY MR. O'CONNOR:

20 Q. All right. Welcome back.
21 We're almost done for the day anyway.

22 Before we broke, you had
23 mentioned information related to patients
24 driving for example, to -- to get

1 medications. In connection with whatever
2 DEA views as manufacturer's obligation to
3 know their customers' customers or report
4 suspicious orders, how is a manufacturer
5 supposed to know if a patient is driving
6 long distances to fill a prescription?

7 A. I think what I had said was
8 depending on the information that you
9 have from the chargeback data, if that
10 information is in there, that would be
11 indicative of diversion.

12 Q. Okay.

13 A. So you would see where the
14 patient came from.

15 Q. Okay. Does -- does the DEA
16 know whether that information is
17 contained in chargeback data?

18 A. Well, that's why I
19 quantified my comment based on, if you
20 have that data in there, that would be
21 indicative of it.

22 Q. Is the DEA aware of whether
23 chargeback data includes completed sales
24 versus open orders?

1 MR. FINKELSTEIN: Scope.

2 THE WITNESS: From --

3 from -- open orders where?

4 BY MR. O'CONNOR:

5 Q. Do you know if chargeback
6 data is retrospective versus prospective?

7 MR. FINKELSTEIN: Scope.

8 THE WITNESS: I don't know.

9 BY MR. O'CONNOR:

10 Q. Backing up a bit. In the
11 DEA's view, do non-registrants have any
12 obligation to monitor for suspicious
13 orders?

14 A. Non-registrants, they're not
15 part of the closed system of
16 distribution.

17 Q. Is DEA aware of whether
18 chargeback data reflects prescriptions?

19 A. Depending on whatever format
20 or information you're getting from them,
21 so you're the one getting the
22 information, so you would -- you would
23 know. We would know if we put a subpoena
24 on you and said, "What information do you

1 have?"

2 Q. But as you sit here today,
3 you do not know whether chargeback data
4 typically includes prescription
5 information?

6 MS. SINGER: Objection.

7 Scope.

8 BY MR. O'CONNOR:

9 Q. You can answer.

10 A. Yeah, I don't know.

11 Q. Earlier today, you testified
12 regarding suspicious order monitoring
13 programs that exist on paper but aren't
14 implemented. I believe you indicated
15 that whether the program actually
16 functioned was more important than
17 whether it existed on paper, correct?

18 MS. SINGER: Objection.

19 Mischaracterizes witness's
20 testimony.

21 THE WITNESS: I don't think
22 I said that.

23 BY MR. O'CONNOR:

24 Q. Okay. Would you agree with

1 me that the way -- the way the program
2 functioned, is more important than what's
3 described on paper?

4 MR. FINKELSTEIN: Vague.

5 THE WITNESS: I don't know.

6 You'd have to assess both to see.

7 I mean, you would hope that it
8 would function better, yes.

9 BY MR. O'CONNOR:

10 Q. Because what matters is
11 whether the program identifies suspicious
12 orders when they come in, correct?

13 MR. FINKELSTEIN: Objection.
14 Vague.

15 THE WITNESS: What matters
16 is, do you have an effective means
17 to safeguard against diversion.
18 That's what matters, because we're
19 trying to protect the public.

20 BY MR. O'CONNOR:

21 Q. Does it say anywhere in the
22 relevant regulations that registrants are
23 required to have a written policy with
24 respect to suspicious order monitoring?

1 A. No.

2 Q. Okay. You spent some time
3 in the liaison policy -- or the policy
4 liaison section, correct?

5 A. Correct.

6 Q. And could you describe for
7 me the modes of communication that that
8 office or other offices used to
9 communicate guidance to the registrant
10 community?

11 MR. FINKELSTEIN: Objection.
12 Vague.

13 THE WITNESS: The -- it's
14 basically two sections, or units.
15 One is policy and the other one is
16 liaison. I was in the liaison
17 section. So that would be the
18 interact -- pretty much the
19 physical interaction with people,
20 whether it's registrants or
21 associations, that type, you know,
22 where we're physically meeting
23 with them or physically doing
24 conferences, doing presentations,

1 going to association meetings and
2 doing a table.

3 That would be -- that would
4 be what we did in liaison; whereas
5 in policy, those would be the
6 questions that came in, whether
7 e-mail, letters, asking specifics
8 about interpretations, asking --
9 seeking waivers for, you know, it
10 could be for an employment waiver,
11 somebody that's been, you know,
12 convicted of a drug felon, and
13 asking for a waiver. It could be
14 that type of communication.

15 So that would be more
16 written. Sometimes it's oral.
17 They would go with us to do some
18 tables and stuff like that.

19 BY MR. O'CONNOR:

20 Q. Okay. And so sometimes it
21 was the in-person communication. Is it
22 fair to say that DEA could also
23 communicate with registrants through
24 written letters?

1 A. Absolutely. And that would
2 be our policy section.

3 Q. And DEA could also issue
4 formal guidance documents if it chose,
5 correct?

6 A. Correct.

7 Q. It could also engage in
8 notice-and-comment rulemaking, right?

9 A. Yes. That's a different
10 section though.

11 Q. It could also post guidance
12 on its website, correct?

13 A. Correct.

14 Q. With the exception of the
15 Rannazzisi letters in 2006 and 2007, DEA
16 did not take any of those steps with
17 respect to communicating guidance on
18 suspicious order monitoring to
19 manufacturers, true?

20 MR. FINKELSTEIN: Objection.
21 Mischaracterizes prior testimony.

22 THE WITNESS: No. I mean we
23 did meet with a few of the
24 manufacturers and went over their

1 data with them. So that was
2 individual.

3 So we did sit down with
4 those that -- when we went through
5 the ARCOS data, there were
6 abnormalities to it. So those are
7 the ones that we met with to
8 discuss that.

9 So we went over their duties
10 and responsibilities with them.

11 BY MR. O'CONNOR:

12 Q. But with certain individual
13 registrants?

14 A. Correct.

15 Q. But other than the two
16 letters from Mr. Rannazzisi, DEA did not
17 send any letters to registrants regarding
18 their obligation under the suspicious
19 order monitoring program, correct?

20 A. Written letters, correct.

21 Q. And DEA did not post any
22 guidance with respect to suspicious order
23 monitoring on its website, did it?

24 MR. FINKELSTEIN: Objection.

1 Form.

2 THE WITNESS: That's
3 correct.

4 BY MR. O'CONNOR:

5 Q. And DEA did not engage in
6 notice-and-comment rulemaking to provide
7 further guidance on suspicious order
8 monitoring to registrants, correct?

9 A. I am not -- I'm not in the
10 reg drafting section. So I don't know if
11 they -- the letter that we saw earlier
12 today, I'm not sure if that was --

13 Q. But since 1974 --

14 A. -- in there.

15 Q. I'm sorry.

16 But since 1974, DEA has not
17 promulgated any regulation providing
18 further guidance to registrants on the
19 supposed obligation to monitor and report
20 suspicious orders, correct?

21 A. Correct.

22 Q. With respect to suspicious
23 order monitoring, does DEA agree that
24 providing registrants with clear guidance

1 is important?

2 A. I think clear guidance is
3 very important.

4 Q. Okay. Would you agree that
5 the clearest guidance is through
6 notice-and-comment rulemaking?

7 MR. FINKELSTEIN: Objection.
8 Vague.

9 THE WITNESS: Could be. I
10 don't know that I completely agree
11 with it. Yes could be.

12 MR. O'CONNOR: We'll mark
13 Exhibit 10.

14 (Document marked for
15 identification as Exhibit
16 DEA-Prevoznik-10.)

17 BY MR. O'CONNOR:

18 Q. Take a moment to look at
19 that. Exhibit 10 is a memorandum from
20 the Attorney General of the United States
21 dated November 16, 2017.

22 Are you familiar with this
23 document?

24 A. No.

1 Q. I'll direct your attention
2 to the last sentence of the second
3 paragraph where it says, "Not only is
4 notice-and-comment rulemaking generally
5 required by law, but it has the benefit
6 of availing agencies of more complete
7 information about a proposed rule's
8 effects than the agency could ascertain
9 on its own and, therefore, results in
10 better decisionmaking by regulators."

11 With respect to suspicious
12 order monitoring and knowing your
13 customer's customer, would you agree that
14 notice-and-comment rulemaking would
15 result in better decisionmaking by
16 regulators?

17 MR. FINKELSTEIN: Asked and
18 answered.

19 BY MR. O'CONNOR:

20 Q. You can answer the question.

21 A. Answer the question?

22 MR. FINKELSTEIN: Yeah.

23 Answer the question.

24 THE WITNESS: Could you

1 repeat it? Sorry.

2 BY MR. O'CONNOR:

3 Q. Sure. With respect to
4 suspicious order monitoring and knowing
5 your customers' customer, would you agree
6 that notice-and-comment rulemaking would
7 result in better decisionmaking by
8 regulators?

9 MS. SINGER: Objection.

10 Asked and answered.

11 THE WITNESS: I -- I don't
12 know. I mean, it says that here.
13 Yes, it's nice to get the -- the
14 opinions and all that. But you
15 get varying opinions from the
16 regulators. You get varying
17 opinions from different --
18 different people as well. So
19 sometimes it can be -- it could be
20 confusing. But it also could be
21 helpful. So, yes. So open lines
22 of communication are good.

23 BY MR. O'CONNOR:

24 Q. I'd like you to look at the

1 next paragraph in the third sentence.

2 MR. FARRELL: Are you going
3 to skip the first two sentences?

4 MR. O'CONNOR: Yes.

5 MR. FINKELSTEIN: Okay.
6 Which one is the third, just so I
7 know where you --

8 MR. O'CONNOR: It starts
9 with but.

10 MR. FINKELSTEIN: But.

11 BY MR. O'CONNOR:

12 Q. "But guidance may not be
13 used as a substitute for rulemaking. It
14 may not be used to impose new
15 requirements on entities outside the
16 executive branch."

17 With respect to suspicious
18 order monitoring and any obligation to
19 know your customer's customer, do you
20 agree with that statement by the Attorney
21 General?

22 MR. FINKELSTEIN: Objection.
23 Calls for a legal conclusion.
24 Outside the scope. You can answer

1 if you understand.

2 THE WITNESS: I don't quite
3 understand your question.

4 BY MR. O'CONNOR:

5 Q. My question is simply
6 whether you agree with the statement by
7 the Attorney General that guidance may
8 not be used as a substitute for
9 rulemaking and may not be used to impose
10 new requirements on entities outside the
11 executive branch, with respect to
12 suspicious order monitoring or any
13 obligation to know your customer's
14 customer?

15 MR. FINKELSTEIN: Objection.
16 Calls for a legal conclusion. You
17 can answer.

18 THE WITNESS: I'm not sure I
19 understand your question. Can you
20 repeat it?

21 BY MR. O'CONNOR:

22 Q. What -- what aren't you sure
23 about?

24 A. I'm not sure what you're

1 asking me.

2 Q. I'm asking --

3 A. Go ahead.

4 Q. I'm asking if you agree with
5 the statement that guidance may not be
6 used as a substitute for rulemaking. It
7 may not be used to impose new
8 requirements on entities outside the
9 executive branch when it comes to
10 suspicious order monitoring or knowing
11 your customer's customer.

12 MR. FINKELSTEIN: And I'm
13 objecting to the scope and
14 objecting that it calls for a
15 legal conclusion. Subject to
16 those objections, you can answer.

17 THE WITNESS: I guess I'm
18 stuck on and may not be used to
19 impose new requirements. What?
20 Guidance, or rulemaking?

21 BY MR. O'CONNOR:

22 Q. Guidance. Do you agree with
23 the statement that guidance may not be
24 used to impose new requirements on

1 entities outside the executive branch
2 when it comes to suspicious order
3 monitoring or knowing your customer's
4 customer?

5 MR. FINKELSTEIN: Do you
6 understand the objections?

7 BY MR. O'CONNOR:

8 Q. I just need a yes or no
9 answer.

10 A. Well --

11 MR. FINKELSTEIN: You -- you
12 can answer as you feel like you
13 need to, to answer.

14 THE WITNESS: Okay. I
15 don't -- I don't understand how
16 guidance is a new requirement.
17 Rulemaking would make a new
18 requirement.

19 So I think what you're
20 asking me is the opposite of what
21 you're looking for. Because
22 guidance is not going to create a
23 new rule.

24 BY MR. O'CONNOR:

1 Q. So it's -- just to be clear,
2 do you agree that guidance may not be
3 used to impose new requirements when it
4 comes to suspicious order monitoring or
5 knowing your customer's customer?

6 MR. FINKELSTEIN: Now we're
7 way outside the scope. I'll --
8 I'll let you answer it.

9 THE WITNESS: One more time.
10 Repeat it. Sorry.

11 BY MR. O'CONNOR:

12 Q. Do you agree that guidance
13 may not be used to impose new
14 requirements when it comes to suspicious
15 order monitoring or knowing your
16 customer's customer?

17 MS. SINGER: Objection.
18 Scope. And calls for a legal
19 opinion.

20 MR. FINKELSTEIN: Scope.
21 I'll stipulate that the witness
22 hasn't been briefed on Seminole
23 Rock or Skidmore or any of that.
24 But you can answer.

1 MR. FARRELL: Who is
2 Skidmore?

3 MR. FINKELSTEIN: It's a
4 case.

5 THE WITNESS: I honestly
6 don't know. And I don't
7 understand the question.

8 BY MR. O'CONNOR:

9 Q. So is it DEA's position that
10 when it comes to suspicious order
11 monitoring and knowing your customer's
12 customer, it does not intend to abide by
13 the direction that guidance may not be
14 used to impose new requirements?

15 MR. FARRELL: Objection.
16 That not only misstates the DEA's
17 position here, it misstates its
18 position in the DC circuit court
19 of appeals in the master's case
20 that rejected what you said.

21 MR. O'CONNOR: I'm asking
22 the DEA the question. And I would
23 like DEA's answer.

24 MR. FINKELSTEIN: Hang on,

1 I'm going to object that that's
2 argumentive. But you can answer.

3 THE WITNESS: All right.

4 MR. FINKELSTEIN: Do you
5 need the question back?

6 THE WITNESS: Yeah. It's --
7 you can read it back.

8 (Whereupon, the court
9 reporter read back the requested
10 portion of testimony.)

11 MR. FINKELSTEIN: The
12 objection was that it was
13 argumentive.

14 THE WITNESS: And my
15 understanding of the question is
16 that guidance is not imposing new
17 requirements. It's not -- it's
18 not imposing them.

19 BY MR. O'CONNOR:

20 Q. And guidance should not
21 impose new requirements, correct?

22 MR. FINKELSTEIN: Objection.
23 Scope. Legal conclusion.

24 Next one I'm going to

1 instruct him not to answer.

2 THE WITNESS: One more time
3 with yours.

4 BY MR. O'CONNOR:

5 Q. And guidance should not
6 impose new requirements, correct?

7 A. I don't believe guidance
8 is -- any guidance is imposing new
9 requirements.

10 Q. Okay.

11 A. It's still falling in the
12 parameters of the statute. You need to
13 have effective means of safeguarding
14 diversion.

15 Q. Going back to ARCOS data.
16 Does the DEA rely on any
17 computer-assisted technology when
18 analyzing ARCOS data?

19 MR. FINKELSTEIN: Objection.
20 Vague.

21 THE WITNESS: What was the
22 question?

23 BY MR. O'CONNOR:

24 Q. Does the DEA rely on any

1 computer-assisted technology when
2 analyzing ARCOS data?

3 A. Computer-assisted
4 technology, what does that mean?

5 Q. Does the DEA when analyzing
6 ARCOS data use a computer, let's start
7 there?

8 A. Yes. We use a computer.

9 Q. Do they use a particular
10 computer program?

11 A. Yes.

12 Q. Okay. What is that program?

13 A. Cognos.

14 Q. Okay. And do they use that
15 program to run any sort of algorithms
16 over the ARCOS data?

17 A. I don't know -- Cognos is
18 used to summarize and aggregate large
19 volumes of data.

20 MR. FARRELL: I'm sorry. I
21 don't mean to interrupt. Can you
22 ask him to spell that?

23 THE WITNESS: Cognos?

24 C-O-G-N-U-S. Cognos. Or N-O-S.

1 BY MR. O'CONNOR:

2 Q. You testified earlier that
3 DEA sometimes uses ARCOS data to generate
4 leads for an investigation. Do you
5 recall that testimony?

6 A. Yes.

7 Q. How does the DEA generate
8 leads from the ARCOS data?

9 MR. FINKELSTEIN: Instruct
10 you not to answer to the extent
11 that your answer calls for law
12 enforcement-sensitive information.
13 Do you understand?

14 THE WITNESS: Yes. Based on
15 that I will not answer that
16 question.

17 BY MR. O'CONNOR:

18 Q. Does -- does the DEA engage
19 in any kind of statistical analysis with
20 respect to ARCOS data?

21 A. It's on our statistical
22 summary -- retail summary reports that
23 are posted on our website. So that
24 analysis is kind of first look --

1 Q. Do you know if DEA applies
2 any sort of regression analysis, for
3 example?

4 A. What kind of?

5 Q. Regression analysis?

6 A. What's that?

7 Q. Okay. It's a type of
8 statistical analysis. Fair to say that
9 DEA does not apply a regression analysis?

10 MR. FINKELSTEIN: Hang on.

11 Objection. The witness just said
12 that he doesn't understand.

13 THE WITNESS: I don't know.

14 BY MR. O'CONNOR:

15 Q. So you're not sure whether
16 DEA applies any kind of statistical
17 analysis?

18 A. No. We do some statistical
19 analysis, but I don't know if it's
20 regression analysis, on what analysis.

21 (Document marked for
22 identification as Exhibit
23 DEA-Prevoznik-11.)

24 BY MR. O'CONNOR:

1 Q. Marking Exhibit 11, which is
2 a report from the Energy and Commerce
3 Committee, House of Representatives.

4 MR. FARRELL: Andrew, what
5 is it, the number?

6 MR. O'CONNOR: 11.

7 MR. FARRELL: You guys are
8 doing all my work for me tomorrow.

9 MR. O'CONNOR: Like to give
10 you a head start, Paul.

11 BY MR. O'CONNOR:

12 Q. Do you recognize this
13 document?

14 A. Yes.

15 Q. What is it?

16 A. It's the Energy and
17 Commerce, "Report on red flags and
18 warning signs. Ignored opioid
19 distribution and enforcement concerns of
20 West Virginia."

21 Q. Okay. If you would turn to
22 Page 11. I take that back. It's
23 actually Page 10. I apologize.

24 Turn your attention to the

1 fifth bullet point. "Prior to 2010, DEA
2 primarily used ARCOS data reactively in
3 enforcement cases."

4 Do you agree with that
5 statement?

6 A. Yes.

7 Q. "According to DEA, technical
8 limitations and data errors made it
9 difficult for DEA to utilize ARCOS data
10 to identify investigative leads."

11 Do you agree?

12 A. Yeah. Yeah. I mean, it
13 made it slightly difficult.

14 Q. And in the next bullet, it
15 says, "Had DEA more proactively used
16 ARCOS data, it could have discovered that
17 between 2006 and 2012, distributors
18 shipped more than 30" -- or "13 million
19 doses of hydrocodone and oxycodone to
20 Sav-Rite Pharmacy Number 1."

21 Do you agree with that
22 statement?

23 MR. FINKELSTEIN: Objection.
24 Scope.

1 BY MR. O'CONNOR:

2 Q. It relates to the analysis
3 of ARCOS data. Can you answer the
4 question?

5 MR. FINKELSTEIN: With
6 respect to a particular pharmacy,
7 it's outside the scope.

8 But you can answer.

9 THE WITNESS: Yes. But I
10 would like to point out between
11 2006, that six years, we came off
12 the mainframe in fall of 2009.

13 MR. FARRELL: Since we are
14 on this topic, can we figure out
15 which distributors the DEA should
16 have investigated with that ARCOS
17 data?

18 MR. O'CONNOR: You'll get
19 your chance tomorrow, Paul.

20 BY MR. O'CONNOR:

21 Q. Let's look at -- I'm going
22 to mark, actually, another exhibit.

23 (Document marked for
24 identification as Exhibit

1 DEA-Prevoznik-12.)

2 BY MR. O'CONNOR:

3 Q. It's two pages.

4 MR. FINKELSTEIN: Wait till
5 we all have it. Counsel, what's
6 been marked as Exhibit 12, we're
7 going to ask to clawback.

8 MR. O'CONNOR: Okay. On the
9 basis of?

10 MR. FINKELSTEIN: On the
11 basis of attorney/client and
12 deliberative process privilege.
13 We believe that it was produced
14 inadvertently.

15 MR. EPPICH: What's the
16 Bates number on that?

17 MR. FINKELSTEIN: DEA 10892.

18 MR. FARRELL: Can we keep a
19 copy? Is it okay if I keep a
20 copy?

21 MR. FINKELSTEIN: I mean,
22 look, it's in the database. But
23 we're attempting to claw it back.

24 MR. FARRELL: Okay. Well,

1 procedurally you can talk to Enu.

2 MR. FINKELSTEIN: What
3 should we talk about?

4 MR. O'CONNOR: Okay. So
5 we're reserving our rights to ask
6 questions about this document
7 we're -- we were just discussing.

8 I won't ask questions about
9 the document. But I do have a
10 couple of questions on the subject
11 of suspicious order reports.

12 BY MR. O'CONNOR:

13 Q. Would you agree that
14 suspicious order reports are not
15 maintained by DEA consistently throughout
16 the field division?

17 MR. FINKELSTEIN: Oh, well,
18 since we're clawing it back, I'm
19 going to take the document from
20 you. Don't worry about it.

21 THE WITNESS: Oh, so don't
22 look at it?

23 MR. FINKELSTEIN: Yeah.

24 THE WITNESS: Okay.

1 MR. FINKELSTEIN: Don't
2 testify based on the document for
3 now.

4 THE WITNESS: Okay.

5 MR. O'CONNOR: Yeah.

6 MR. FINKELSTEIN: Can you
7 repeat your question for me?

8 BY MR. O'CONNOR:

9 Q. Sure. So in the DEA's view,
10 were suspicious order reports maintained
11 consistently across the field offices?

12 A. No.

13 MR. FINKELSTEIN: Objection.
14 Vague.

15 THE WITNESS: Sorry.

16 MR. FINKELSTEIN: Go ahead.

17 THE WITNESS: No.

18 BY MR. O'CONNOR:

19 Q. And were suspicious order
20 reports shared in a systematic way across
21 the field offices?

22 MR. FINKELSTEIN: Objection.
23 Vague.

24 THE WITNESS: I mean, I

1 testified earlier that we would
2 break it up by AOR, and then it's
3 the field's responsibility to
4 review and deem whatever action
5 they deem necessary. So -- so
6 those that went to the field,
7 that's how they are handled.

8 BY MR. O'CONNOR:

9 Q. Okay. But as a matter of
10 practice and policy, were suspicious
11 order reports submitted to one field
12 office necessarily transmitted to all the
13 others?

14 MR. FINKELSTEIN: Scope.

15 You can answer.

16 THE WITNESS: Can you repeat
17 it?

18 BY MR. O'CONNOR:

19 Q. Sure. As a matter of
20 practice and policy, were suspicious
21 order reports submitted to one field
22 office necessarily transmitted to all of
23 the others?

24 A. From my personal experience,

1 I know that's what we did.

2 Q. Okay. And speaking for DEA,
3 can you testify here today that as a
4 matter of practice, suspicious order
5 reports that were submitted to one field
6 office were always distributed to the
7 other field offices around the country?

8 MR. FINKELSTEIN: Vague as
9 to time and scope.

10 THE WITNESS: I'm not
11 comfortable with the word
12 "always." Those people that I did
13 talk to about how this was done,
14 that's how they said it was done,
15 that they would send it off to the
16 respective field offices. But I
17 can't answer for every single
18 investigator out there.

19 BY MR. O'CONNOR:

20 Q. You can't say in every case
21 that every suspicious order report was
22 shared across the various field offices?

23 A. Correct.

24 Q. If a registrant did not meet

1 its obligations to report suspicious
2 orders, does the DEA have authority to
3 suspend or revoke it's registration?

4 A. I'm sorry?

5 Q. If a registrant does not
6 meet its obligations to report suspicious
7 orders, does the DEA have authority to
8 suspend or revoke its registration?

9 A. It would fall under -- not
10 specifically that, that wording. But it
11 would fall under 823, that -- for failure
12 to maintain effective controls over
13 diversion.

14 Q. If a registrant were failing
15 to report suspicious orders in such a way
16 that DEA believed it posed a threat to
17 the public health, would it seek to
18 suspend or revoke that registrant's
19 registration?

20 MR. FINKELSTEIN: Objection.
21 Incomplete hypothetical.

22 THE WITNESS: There is a
23 wide variety of things that we --
24 that we could do. We could take

1 administrative actions. We could
2 take civil actions. We could move
3 to do an order to show cause. If
4 we could show that there was
5 imminent danger to the public --
6 public, we could go for immediate
7 suspension order. We can do an
8 injunctive action with the civil,
9 or we can take criminal action.
10 So there's a wide variety of
11 different ways we could go about
12 it.

13 BY MR. O'CONNOR:

14 Q. So it's fair to say that if
15 the DEA believed a registrant posed a
16 risk to the public health because it was
17 failing to report suspicious orders, it
18 would take some sort of action, correct?

19 A. Yes, correct.

20 MR. O'CONNOR: If we can
21 just take a couple-minute break.

22 MR. FINKELSTEIN: Okay, but
23 we've got a hard stop at 6:00.

24 MR. O'CONNOR: Understood.

1 THE VIDEOGRAPHER: 5:43. We
2 are off the video record.

3 (Short break.)

4 THE VIDEOGRAPHER: 5:49. We
5 are on the video record.

6 THE WITNESS: If I could,
7 just before we begin. I -- I
8 believe I misstated something in
9 your -- one of the last questions.

10 I think you said that did we
11 disperse out the suspicious orders
12 to all field's -- field offices,
13 that was -- that's not correct.
14 We wouldn't -- we would send it to
15 the respective AORs. I just
16 wanted to clarify.

17 BY MR. O'CONNOR:

18 Q. Okay. So the suspicious
19 order reports were not sent to all field
20 offices, just to the --

21 A. To the relevant one that
22 it -- that -- into that -- where that
23 registrant was.

24 Q. So it would go to where the

1 reporting registrant was?

2 A. So it would -- say the
3 reporter is in Pennsylvania and who they
4 are reporting on is in New Jersey. It
5 would go to the New Jersey office. It
6 wouldn't go all across country.

7 Thank you.

8 - - -

9 EXAMINATION

10 - - -

11 BY MR. STEPHENS:

12 Q. Mr. Prevoznik, good
13 afternoon. My name is Neal Stephens, I'm
14 with the Jones Day law firm. And I
15 represent Walmart. I will be asking you
16 some questions on behalf of retail chain
17 pharmacies, which will include Walmart,
18 CVS, Rite Aid, Walgreens and HBC Giant
19 Eagle.

20 A. Okay.

21 Q. What I'd like to do is I'd
22 like to start by asking you a few
23 questions about DEA's interpretation and
24 enforcement of some of the relevant

1 provisions of the Controlled Substances
2 Act. Okay?

3 A. Okay.

4 Q. And including some basic
5 introductory questions to understand
6 DEA's mission under the Controlled
7 Substances Act, which you testified a
8 little bit earlier today, right?

9 A. Correct.

10 Q. Okay. Now, for DEA's
11 diversion control unit, the mission has
12 two core elements, right, to prevent the
13 diversion of controlled substances while,
14 secondly, ensuring an adequate supply for
15 legitimate medical needs, true?

16 A. True.

17 Q. And the Controlled
18 Substances Act is drafted with those two
19 goals in mind, true?

20 MR. FINKELSTEIN: Calls for
21 speculation.

22 THE WITNESS: That would be
23 my understanding.

24 BY MR. STEPHENS:

1 Q. Okay. So let's start with
2 the second piece of that, ensuring an
3 adequate supply. Are you with me?

4 A. Yes.

5 Q. All right. As to ensuring
6 an adequate supply, for legitimate
7 medical needs, Title 21 U.S.C. 801 states
8 that "many of the drugs included within
9 the subchapter have a useful and
10 legitimate medical purpose and are
11 necessary to maintain the health and
12 general welfare of the American people."

13 Is that your understanding
14 of Title 21 U.S.C. 801?

15 MR. FINKELSTEIN: Scope.

16 You can answer.

17 THE WITNESS: Yes.

18 BY MR. STEPHENS:

19 Q. Okay. And that provision
20 refers to drugs, right, the word drugs?

21 A. Yes.

22 Q. Okay.

23 Prescription opioids would
24 be some of those drugs that are referred

1 to in that provision we just covered,
2 right?

3 A. Yes.

4 Q. All right. DEA agrees that
5 chronic pain is a serious problem for
6 many Americans, true?

7 MS. SINGER: Objection.
8 Scope.

9 THE WITNESS: Yeah, people
10 have back pain.

11 BY MR. STEPHENS:

12 Q. And DEA also agrees that
13 it's crucial for physicians who are
14 engaged in legitimate pain treatment not
15 to be discouraged from providing proper
16 medication to patients as medically
17 justified?

18 MR. FINKELSTEIN: Scope.

19 MS. SINGER: Objection.
20 Scope.

21 THE WITNESS: Yes.

22 BY MR. STEPHENS:

23 Q. Okay. And DEA agrees that
24 opioids, properly prescribed by DEA

1 registered medical doctors, are an
2 appropriate medication for many
3 Americans?

4 MS. SINGER: Objection.
5 Scope.

6 MR. FINKELSTEIN: Scope.
7 Incomplete hypothetical.

8 THE WITNESS: Yes.

9 BY MR. STEPHENS:

10 Q. DEA also agrees that there's
11 a legitimate medical need under Title 21
12 U.S.C. 801 for prescription opioids to
13 treat pain in patients in the United
14 States?

15 MS. SINGER: Objection.
16 Scope.

17 THE WITNESS: For a
18 legitimate medical purpose, yes.

19 BY MR. STEPHENS:

20 Q. DEA also agrees that
21 prescription opioids are necessary to
22 maintain the health of the American
23 people?

24 MS. SINGER: Objection.

1 MR. FINKELSTEIN: Scope.

2 THE WITNESS: For all the
3 American people or those that need
4 it?

5 BY MR. STEPHENS:

6 Q. Those that need it.

7 A. Those that need it, yes.

8 Q. Okay. And DEA also agrees
9 that prescription opioids are necessary
10 to maintain the general welfare of
11 American people who need them?

12 A. Correct.

13 Q. Patients who are properly
14 prescribed opioid medications should be
15 able to obtain their medications from a
16 pharmacy?

17 MS. SINGER: Objection.

18 Scope.

19 I think this has been a long
20 line of questions outside of the
21 scope. And at some point I'd
22 request that DOJ instruct the
23 witness.

24 MR. FINKELSTEIN: I agree

1 that this is outside the scope.

2 I'll let the witness answer for
3 now if you have understanding.

4 THE WITNESS: Yes.

5 BY MR. STEPHENS:

6 Q. Is it also true under -- you
7 testified earlier today about the C.F.R.
8 regulations, correct?

9 A. Correct.

10 Q. And under Title 21 -- or I'm
11 sorry, under 21 C.F.R. 1301.71(b), it's
12 true that the regulation regarding
13 suspicious order monitoring does not
14 require strict compliance, it requires
15 substantial compliance?

16 MR. FINKELSTEIN: Did you
17 mean 74?

18 MR. STEPHENS: It might be
19 74.

20 MR. FARRELL: 1301.74(b)?

21 MR. STEPHENS: Yes. No,
22 actually -- here. Let me just
23 mark it.

24 (Document marked for

1 identification as Exhibit

2 DEA-Prevoznik-13.)

3 BY MR. STEPHENS:

4 Q. I'll show the witness what's
5 been marked as Exhibit 13.

6 A. So, (b)?

7 Q. (B), right.

8 A. Okay.

9 Q. So (b) states substantial
10 compliance with the standards set forth,
11 right?

12 A. Yes.

13 Q. Okay. And that could be
14 deemed sufficient, correct?

15 A. Yes. That's what it says.

16 Q. It does not say strict
17 compliance, correct?

18 A. Correct.

19 Q. Like manufacturers and
20 distributors, DEA also considers doctors
21 who prescribe opioids to their patients
22 to be registrants?

23 A. Correct.

24 Q. Okay. The prescribing

1 doctors have an obligation under the
2 Controlled Substances Act to prescribe
3 opioids responsibly so the controlled
4 substances will not be diverted, true?

5 MR. FINKELSTEIN: Scope.

6 THE WITNESS: Yes.

7 BY MR. STEPHENS:

8 Q. Do you agree that
9 prescribers are the registrants who are
10 best situated to assess whether a patient
11 has a legitimate medical need for
12 prescription opioids?

13 MR. FINKELSTEIN: Scope.

14 MS. SINGER: Objection.

15 Scope.

16 THE WITNESS: It has to be
17 in the course of their usual
18 practice and for a legitimate
19 medical purpose. So it has to be
20 under those guise. If they're
21 writing prescriptions just to
22 write prescriptions and not
23 practicing medicine, then I would
24 disagree.

1 BY MR. STEPHENS:

2 Q. Okay. But prescribers, not
3 manufacturers, distributors, or
4 pharmacists are required to have medical
5 degrees, right?

6 A. That's correct.

7 Q. Okay. And the physicians,
8 not manufacturers, distributors, or
9 pharmacists, are licensed to practice
10 medicine, right?

11 A. Correct.

12 Q. Okay. And it's the
13 physicians, not manufacturers,
14 distributors, or pharmacists, that have
15 full access to a patient's MRI results,
16 their blood test work and other medical
17 test results?

18 MS. SINGER: Objection.
19 Scope.

20 MR. FINKELSTEIN: Incomplete
21 hypothetical.

22 THE WITNESS: If all those
23 things are done.

24 BY MR. STEPHENS:

1 Q. DEA by agreeing to provide a
2 registration to a physician has provided
3 the doctor with the authority to write
4 prescriptions to patients for controlled
5 substances like opioids?

6 MR. FINKELSTEIN: Scope.

7 I'm going to note for the record
8 that this is line of questions
9 with respect to a CSA section that
10 the witness has not been
11 authorized to testify about.

12 But since the witness is
13 familiar with this section, I'll
14 let him answer the question.

15 THE WITNESS: Can you please
16 repeat it.

17 BY MR. STEPHENS:

18 Q. Sure. DEA, by agreeing to
19 provide a registration to a physician,
20 has provided the doctor with the
21 authority to write prescriptions to
22 patients for controlled substances like
23 opioids?

24 A. Yes. But some -- some may

1 not be authorized to write for opioids
2 because they've gotten in trouble. It
3 depends on their state authority. It
4 depends on whether we've taken an action
5 against them. So there could be some
6 limitations on what they are allowed to
7 prescribe and what schedules. We could
8 limit their schedules as well.

9 Q. Okay. I'm talking about a
10 doctor with an active registration with
11 DEA.

12 A. Well, I mean, you can still
13 have an active DEA registration and be
14 limited on what schedule you're allowed
15 to do or what things you're not allowed
16 to do. So your DEA registration can be
17 active, but there could be limitations or
18 restrictions on it.

19 Q. Okay. As to prescription
20 opioids DEA believes that the
21 overwhelming majority of prescribing in
22 America is conducted responsibly?

23 MS. SINGER: Objection.
24 Scope.

1 MR. FINKELSTEIN: Scope.

2 THE WITNESS: Can you please
3 repeat it.

4 BY MR. STEPHENS:

5 Q. Sure. As to prescription
6 opioids, DEA believes that the
7 overwhelming majority of prescribing in
8 America is conducted responsibly?

9 A. Yes, correct.

10 Q. And DEA has stated that
11 99.5 percent of prescribers do not
12 overprescribe opioids?

13 MR. FINKELSTEIN: Scope.

14 You can answer if you know.

15 THE WITNESS: I don't know
16 that we said 99.5 percent. I've
17 heard the figure 1 to 2 percent.

18 BY MR. STEPHENS:

19 Q. Okay. Well, let me show you
20 the transcript.

21 MR. FARRELL: Can you
22 reference the transcript, please.

23 MR. STEPHENS: Yes, sir.

24 (Document marked for

1 identification as Exhibit

2 DEA-Prevoznik-14.)

3 BY MR. STEPHENS:

4 Q. The transcript is dated
5 April 29, 2014. It's a subcommittee
6 hearing on oversight investigations by
7 the Committee of Energy and Commerce.

8 MR. FINKELSTEIN: We're at
9 6:00. I'll let you ask this
10 question and then we're going to
11 break for the day.

12 BY MR. STEPHENS:

13 Q. I'd ask you to turn to Page
14 76.

15 A. Page 76.

16 Q. Page 76, Mr. Prevoznik. And
17 we're looking at, like, the
18 second-to-last paragraph where
19 Mr. Rannazzisi is talking.

20 Do you see that?

21 A. Mm-hmm.

22 Q. And there's a question from
23 a Mr. Burgess ahead of that, correct?

24 Do you see that?

1 A. Yes.

2 Q. Okay. And Mr. Burgess says
3 something to the effect that
4 Mr. Rannazzisi seems to imply that we are
5 overprescribing. Mr. Rannazzisi then
6 responds and says, "I think that if you
7 are talking about 99.5 percent of the
8 prescribers, no, they are not
9 overprescribing. But our focus is in
10 rogue pain clinics and rogue doctors who
11 are overprescribing."

12 Did I read that accurately?

13 A. Yes.

14 Q. Okay. So my question for
15 you, the initial question was, DEA has
16 publicly stated that 99.5 percent of the
17 prescribers are not overprescribing,
18 correct?

19 A. Correct.

20 MR. STEPHENS: All right.
21 That's all I have for the day.

22 MR. FINKELSTEIN: We're
23 going to excuse the witness so we
24 can argue about what's going to

1 happen tomorrow.

2 THE VIDEOGRAPHER: 6:01 p.m.

3 We are off the video record.

4 MS. MAINIGI: The only thing
5 that I want to put on the record
6 is the defendants are reserving
7 time for recross as we have in all
8 other DEA depositions.

9 MR. FARRELL: The plaintiffs
10 reserve the right to recross the
11 recross since we'll be calling the
12 witness in our case in chief.

13 MS. MAINIGI: I think you
14 have done that before, so that's
15 fine, and I think it's just a
16 matter of scope.

17 MR. FARRELL: Matter of
18 what?

19 MS. MAINIGI: Scope.

20 (Excused.)

21 (Deposition concluded at
22 approximately 6:03 p.m.)

23

24

1
2 CERTIFICATE
3
4

5 I HEREBY CERTIFY that the
6 witness was duly sworn by me and that the
7 deposition is a true record of the
8 testimony given by the witness.

9 It was requested before
10 completion of the deposition that the
11 witness, THOMAS PREVOZNIK, have the
12 opportunity to read and sign the
13 deposition transcript.

14
15 
16 _____

17 MICHELLE L. GRAY,
18 A Registered Professional
19 Reporter, Certified Shorthand
20 Reporter, Certified Realtime
21 Reporter and Notary Public
22 Dated: April 22, 2019
23
24

(The foregoing certification
of this transcript does not apply to any
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supervision of the certifying reporter.)

1 INSTRUCTIONS TO WITNESS

2
3 Please read your deposition
4 over carefully and make any necessary
5 corrections. You should state the reason
6 in the appropriate space on the errata
7 sheet for any corrections that are made.

8 After doing so, please sign
9 the errata sheet and date it.

10 You are signing same subject
11 to the changes you have noted on the
12 errata sheet, which will be attached to
13 your deposition.

14 It is imperative that you
15 return the original errata sheet to the
16 deposing attorney within thirty (30) days
17 of receipt of the deposition transcript
18 by you. If you fail to do so, the
19 deposition transcript may be deemed to be
20 accurate and may be used in court.

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		E R R A T A
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4	PAGE	LINE CHANGE
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24	REASON:	_____

1
2 ACKNOWLEDGMENT OF DEPONENT

3
4 I, _____, do
5 hereby certify that I have read the
6 foregoing pages, 1 - 409, and that the
7 same is a correct transcription of the
8 answers given by me to the questions
9 therein propounded, except for the
10 corrections or changes in form or
11 substance, if any, noted in the attached
12 Errata Sheet.

13
14
15 _____
16 THOMAS PREVOZNIK

DATE

17
18
19 Subscribed and sworn
to before me this

20 _____ day of _____, 20____.

21 My commission expires: _____

22
23 _____
24 Notary Public

	LAWYER'S NOTES		
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